should not be sprung to return to a lifted position.

(c) A grab bar at least 24 inches (610 mm) long should be mounted behind the water closet, and a horizontal grab bar at least 40 inches (1015 mm) long should be mounted on at least one side wall, with one end not more than 12 inches (305 mm) from the back wall, at a height between 33 inches (840 mm) and 36 inches (915 mm) above the floor.

(d) Faucets and flush controls should be operable with one hand and should not require tight grasping, pinching, or twisting of the wrist. The force required to activate controls should be no greater than 5 lbs (22.2 N). Controls for flush valves should be mounted no more than 44 inches (1120 mm) above the floor.

(e) Doorways on the end of the enclosure, opposite the water closet, should have a minimum clear opening width of 32 inches (815 mm). Door latches and hardware should be operable with one hand and should not require tight grasping, pinching, or twisting of the wrist.

(2) Accessible restrooms should be in close proximity to at least one seating location for persons using mobility aids and should be connected to such a space by an unobstructed path having a minimum width of 32 inches (815 mm).

C. *Visibility Through a Window.* Care should be taken so that the lift does not obscure the vision of the person occupying the securement position.

[56 FR 45756, Sept. 6, 1991, as amended at 63 FR 51702, 51703, Sept. 28, 1998]

EFFECTIVE DATE NOTE: At 63 FR 51702, 51703, Sept. 28, 1998, the appendix to part 38 was amended by adding a new section VI, effective Oct. 28, 1998.

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG TESTING PROGRAMS

Sec.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, 45101–45106.

SOURCE: 54 FR 49866, Dec. 1, 1989, unless otherwise noted.

Subpart A—General

SOURCE: 59 FR 7354, Feb. 15, 1994, unless otherwise noted.

§ 40.1 Applicability.

This part applies, through regulations that reference it issued by agencies of the Department of Transportation, to transportation employers, including self-employed individuals, required to conduct drug and/or alcohol testing programs by DOT agency regulations and to such transportation employers' officers, employees, agents and contractors (including, but not limited to, consortia). Employers are responsible for the compliance of their officers, employees, agents, consortia and/or contractors with the requirements of this part.

§ 40.3 Definitions.

The following definitions apply to this part:

Air blank. A reading by an EBT of ambient air containing no alcohol. (In EBTs using gas chromatography technology, a reading of the device's internal standard.)

Alcohol. The intoxicating agent in beverage alcohol, ethyl alcohol or other low molecular weight alcohols including methyl or isopropyl alcohol.

Alcohol concentration. The alcohol in a volume of breath expressed in terms of grams of alcohol per 210 liters of breath as indicated by a breath test under this part.

Alcohol use. The consumption of any beverage, mixture or preparation, including any medication, containing alcohol.

Aliquot. A portion of a specimen used for testing.

Blind sample or blind performance test specimen. A urine specimen submitted to a laboratory for quality control testing purposes, with a fictitious identifier, so that the laboratory cannot distinguish it from employee specimens, and which is spiked with known quantities of specific drugs or which is blank, containing no drugs.

Breath Alcohol Technician (BAT). An individual who instructs and assists individuals in the alcohol testing process and operates an EBT.

Canceled or invalid test. In drug testing, a drug test that has been declared invalid by a Medical Review Officer. A canceled test is neither a positive nor a negative test. For purposes of this part, a sample that has been rejected for testing by a laboratory is treated the same as a canceled test. In alcohol testing, a test that is deemed to be invalid under § 40.79. It is neither a positive nor a negative test.

Chain of custody. Procedures to account for the integrity of each urine or blood specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. With respect to drug testing, these procedures shall require that an appropriate drug testing custody form (see § 40.23(a)) be used from time of collection to receipt by the laboratory and that upon receipt by the laboratory an appropriate laboratory chain of custody form(s) account(s) for the sample or sample aliquots within the laboratory.

Collection container. A container into which the employee urinates to provide the urine sample used for a drug test.

Collection site. A place designated by the employer where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

Collection site person. A person who instructs and assists individuals at a collection site and who receives and makes a screening examination of the urine specimen provided by those individuals.

Confirmation (or confirmatory) test. In drug testing, a second analytical procedure to identify the presence of a specific drug or metabolite that is independent of the screening test and that uses a different technique and chemical principle from that of the screening test in order to ensure reliability and accuracy. (Gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.) In alcohol testing, a second test, following a screening test with a result of 0.02 or greater, that provides quantitative data of alcohol concentration.

DHHS. The Department of Health and Human Services or any designee of the Secretary, Department of Health and Human Services.

DOT agency. An agency of the United States Department of Transportation administering regulations related to drug or alcohol testing, including the

United States Coast Guard (for drug testing purposes only), the Federal Aviation Administration, the Federal Railroad Administration, the Federal Highway Administration, the Federal Transit Administration, the Research and Special Programs Administration, and the Office of the Secretary.

Employee. An individual designated in a DOT agency regulation as subject to drug testing and/or alcohol testing. As used in this part ''employee'' includes an applicant for employment. ''Employee'' and ''individual'' or ''individual to be tested'' have the same meaning for purposes of this part.

Employer. An entity employing one or more employees that is subject to DOT agency regulations requiring compliance with this part. As used in this part, *employer* includes an industry consortium or joint enterprise comprised of two or more employing entities.

EBT (or evidential breath testing device). An EBT approved by the National Highway Traffic Safety Administration (NHTSA) for the evidential testing of breath and placed on NHTSA's ''Conforming Products List of Evidential Breath Measurement Devices'' (CPL), and identified on the CPL as conforming with the model specifications available from the National Highway Traffic Safety Administration, Office of Alcohol and State Programs.

Medical Review Officer (MRO). A licensed physician (medical doctor or doctor of osteopathy) responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's confirmed positive test result together with his or her medical history and any other relevant biomedical information.

Screening test (or initial test). In drug testing, an immunoassay screen to eliminate ''negative'' urine specimens from further analysis. In alcohol testing, an analytic procedure to determine whether an employee may have a prohibited concentration of alcohol in a breath specimen.

Secretary. The Secretary of Transportation or the Secretary's designee.

Shipping container. A container capable of being secured with a tamper-evident seal that is used for transfer of one or more urine specimen bottle(s) and associated documentation from the collection site to the laboratory.

Specimen bottle. The bottle that, after being labeled and sealed according to the procedures in this part, is used to transmit a urine sample to the laboratory.

Substance abuse professional. A licensed physician (Medical Doctor or Doctor of Osteopathy); or a licensed or certified psychologist, social worker, or employee assistance professional; or an addiction counselor (certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission or by the International Certification Reciprocity Consortium/Alcohol & Other Drug Abuse). All must have knowledge of and clinical experience in the diagnosis and treatment of alcohol and controlled substances-related disorders.

[59 FR 7354, Feb. 15, 1994, as amended at 59 FR 43000, Aug. 19, 1994; 61 FR 37224, July 17, 1996]

§§40.5—40.19 [Reserved]

Subpart B—Drug Testing

§40.21 The drugs.

(a) DOT agency drug testing programs require that employers test for marijuana, cocaine, opiates, amphetamines and phencyclidine.

(b) An employer may include in its testing protocols other controlled substances or alcohol only pursuant to a DOT agency approval, if testing for those substances is authorized under agency regulations and if the DHHS has established an approved testing protocol and positive threshold for each such substance.

(c) Urine specimens collected under DOT agency regulations requiring compliance with this part may only be used to test for controlled substances designated or approved for testing as described in this section and shall not be used to conduct any other analysis or test unless otherwise specifically authorized by DOT agency regulations.

(d) This section does not prohibit procedures reasonably incident to analysis of the specimen for controlled substances (e.g., determination of pH or tests for specific gravity, creatinine concentration or presence of adulterants).

§ 40.23 Preparation for testing.

The employer and certified laboratory shall develop and maintain a clear and well-documented procedure for collection, shipment, and accessioning of urine specimens under this part. Such a procedure shall include, at a minimum, the following:

(a)(1) Except as provided in paragraph (a)(2) of this section, use of the drug testing form prescribed under this part.

(i) This form is found in appendix A to this part.

(ii) Employers and other participants in the DOT drug testing program may not modify or revise this form, except that the drug testing custody and control form may include such additional information as may be required for billing or other legitimate purposes necessary to the collection, provided that personal identifying information on the donor (other than the social security number or other employee ID number) may not be provided to the laboratory.

(iii) Donor medical information may appear only on the copy provided the donor.

(2) Notwithstanding the requirement of paragraph (a)(1)(ii) of this section, employers and other participants may use existing forms that were in use in the DOT drug testing program prior to February 16, 1995, until June 1, 1995.

(b)(1) Use of a clean, single-use specimen bottle that is securely wrapped until filled with the specimen. A clean, single-use collection container (e.g., disposable cup or sterile urinal) that is securely wrapped until used may also be employed. *If urination is directly into the specimen bottle,* the specimen bottle shall be provided to the employee still sealed in its wrapper or shall be unwrapped in the employee's presence immediately prior to its being provided. *If a separate collection container is used for urination,* the collection container shall be provided to the employee still sealed in its wrapper or shall be unwrapped in the employee's presence immediately prior to its being provided; and the collection site person shall unwrap the specimen bottle in the presence of the employee at the time the urine specimen is presented.

(2) Use of a tamperproof sealing system, designed in a manner such to ensure against undetected opening. The specimen bottle shall be identified with a unique identifying number identical to that appearing on the urine custody and control form, and space shall be provided to initial the bottle affirming its identity. For purposes of clarity, this part assumes use of a system made up of one or more preprinted labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(c) Use of a shipping container in which the specimen and associated paperwork may be transferred and which can be sealed and initialled to prevent undetected tampering. If the split specimen option is exercised, the split specimen and associated paperwork shall be sealed in a shipping (or storage) container and initialled to prevent undetected tampering.

(d) Written procedures, instructions and training shall be provided as follows:

(1) Employer collection procedures and training shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the donor, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(2) A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required in this part

(i) A non-medical collection site person shall receive training in compliance with this part and shall demonstrate proficiency in the application

of this part prior to serving as a collection site person. A medical professional, technologist or technician licensed or otherwise approved to practice in the jurisdiction in which the collection takes place is not required to receive such training if that person is provided instructions described in this part and performs collections in accordance with those instructions.

(ii) Collection site persons shall be provided with detailed, clear instructions on the collection of specimens in compliance with this part. Employer representatives and donors subject to testing shall also be provided standard written instructions setting forth their responsibilities.

(3) Unless it is impracticable for any other individual to perform this function, a direct supervisor of an employee shall not serve as the collection site person for a test of the employee. If the rules of a DOT agency are more stringent than this provision regarding the use of supervisors as collection site personnel, the DOT agency rules shall prevail with respect to testing to which they apply.

(4) In any case where a collection is monitored by non-medical personnel or is directly observed, the collection site person shall be of the same gender as the donor. A collection is monitored for this purpose if the enclosure provides less than complete privacy for the donor (e.g., if a restroom stall is used and the collection site person remains in the restroom, or if the collection site person is expected to listen for use of unsecured sources of water.)

[54 FR 49866, Dec. 1, 1989, as amended at 60 FR 19536, Apr. 19, 1995]

§40.25 Specimen collection procedures.

(a) *Designation of collection site.* (1) Each employer drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a certified drug testing laboratory. An independent medical facility may also be utilized as a collection site provided the other applicable requirements of this part are met.

(2) A designated collection site may be any suitable location where a specimen can be collected under conditions set forth in this part, including a properly equipped mobile facility. A designated collection site shall be a location having an enclosure within which private urination can occur, a toilet for completion of urination (unless a single-use collector is used with sufficient capacity to contain the void), and a suitable clean surface for writing. The site must also have a source of water for washing hands, which, if practicable, should be external to the enclosure where urination occurs.

(b) *Security.* The purpose of this paragraph is to prevent unauthorized access which could compromise the integrity of the collection process or the specimen.

(1) Procedures shall provide for the designated collection site to be secure. If a collection site facility is dedicated solely to urine collection, it shall be secure at all times. If a facility cannot be dedicated solely to drug testing, the portion of the facility used for testing shall be secured during drug testing.

(2) A facility normally used for other purposes, such as a public rest room or hospital examining room, may be secured by visual inspection to ensure other persons are not present and undetected access (e.g., through a rear door not in the view of the collection site person) is not possible. Security during collection may be maintained by effective restriction of access to collection materials and specimens. In the case of a public rest room, the facility must be posted against access during the entire collection procedure to avoid embarrassment to the employee or distraction of the collection site person.

(3) If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed mailer is transferred for shipment, the following minimum procedures shall apply. The specimen shall remain under the direct control of the collection site person from delivery to its being sealed in the mailer. The mailer shall be immediately mailed, maintained in secure storage, or remain until mailed under

the personal control of the collection site person.

(c) *Chain of custody*. The chain of custody block of the drug testing custody and control form shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine specimens from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Since specimens and documentation are sealed in shipping containers that would indicate any tampering during transit to the laboratory and couriers, express carriers, and postal service personnel do not have access to the chain of custody forms, there is no requirement that such personnel document chain of custody for the shipping container during transit. Nor is there a requirement that there be a chain of custody entry when a specimen which is sealed in such a shipping container is put into or taken out of secure storage at the collection site prior to pickup by such personnel. This means that the chain of custody is not broken, and a test shall not be canceled, because couriers, express carriers, postal service personnel, or similar persons involved solely with the transportation of a specimen to a laboratory, have not documented their participation in the chain of custody documentation or because the chain of custody does not contain entries related to putting the specimen into or removing it from secure temporary storage at the collection site. Every effort shall be made to minimize the number of persons handling specimens.

(d) *Access to authorized personnel only*. No unauthorized personnel shall be permitted in any part of the designated collection site where urine specimens are collected or stored. Only the collection site person may handle specimens prior to their securement in the mailing container or monitor or observe specimen collection (under the conditions specified in this part). In order to promote security of specimens, avoid distraction of the collection site person and ensure against any confusion in the identification of specimens, the collection site person shall have only one donor under his or her supervision at any time. For this purpose, a collection procedure is complete when the urine bottle has been sealed and initialled, the drug testing custody and control form has been executed, and the employee has departed the site (or, in the case of an employee who was unable to provide a complete specimen, has entered a waiting area).

(e) *Privacy*. (1) Procedures for collecting urine specimens shall allow individual privacy unless there is a reason to believe that a particular individual may alter or substitute the specimen to be provided, as further described in this paragraph.

(2) For purposes of this part, the following circumstances are the exclusive grounds constituting a reason to believe that the individual may alter or substitute the specimen:

(i) The employee has presented a urine specimen that falls outside the normal temperature range (32°–38° C/ 90°–100° F), and

(A) The employee declines to provide a measurement of body temperature (taken by a means other than use of a rectal thermometer), as provided in paragraph (f)(14) of the part; or

(B) Body temperature varies by more than 1°C/1.8°F from the temperature of the specimen;

(ii) The last urine specimen provided by the employee (i.e., on a previous occasion) was determined by the laboratory to have a specific gravity of less than 1.003 and a creatinine concentration below .2g/L;

(iii) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the sample (e.g., substitute urine in plain view, blue dye in specimen presented, etc.); or

(iv) The employee has previously been determined to have used a controlled substance without medical authorization and the particular test was being conducted under a DOT agency regulation providing for follow-up testing upon or after return to service.

(3) A higher-level supervisor of the collection site person, or a designated employer representative, shall review and concur in advance with any decision by a collection site person to obtain a specimen under the direct observation of a same gender collection site person based upon the circumstances

described in subparagraph (2) of this paragraph.

(f) *Integrity and identity of specimen.* Employers shall take precautions to ensure that a urine specimen is not adulterated or diluted during the collection procedure and that information on the urine bottle and on the urine custody and control form can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that unadulterated specimens are obtained and correctly identified:

(1) To deter the dilution of specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. Where practicable, there shall be no other source of water (e.g., shower or sink) in the enclosure where urination occurs. If there is another source of water in the enclosure it shall be effectively secured or monitored to ensure it is not used as a source for diluting the specimen.

(2) When an individual arrives at the collection site, the collection site person shall ensure that the individual is positively identified as the employee selected for testing (e.g., through presentation of photo identification or identification by the employer's representative). If the individual's identity cannot be established, the collection site person shall not proceed with the collection. If the employee requests, the collection site person shall show his/her identification to the employee.

(3) If the individual fails to arrive at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The individual may retain his or her wallet. If the employee requests it, the collection site personnel shall provide the employee a receipt for any personal belongings.

(5) The individual shall be instructed to wash and dry his or her hands prior to urination.

(6) After washing hands, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the specimen.

(7) The individual may provide his/her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy. The collection site person shall provide the individual with a specimen bottle or collection container, if applicable, for this purpose.

(8) The collection site person shall note any unusual behavior or appearance on the urine custody and control form.

(9) In the exceptional event that an employer-designated collection site is not accessible and there is an immediate requirement for specimen collection (e.g., circumstances require a post-accident test), a public rest room may be used according to the following procedures: A collection site person of the same gender as the individual shall accompany the individual into the public rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain of custody procedures.

(10) The collection site person shall instruct the employee to provide at least 45 ml of urine under the split sample method of collection or 30 ml of urine under the single sample method of collection.

(i)(A) Employers with employees subject to drug testing only under the drug testing rules of the Research and Special Programs Administration and/or Coast Guard may use the ''split sample'' method of collection or may collect a single sample for those employees.

(B) Employers with employees subject to drug testing under the drug testing rules of the Federal Highway Administration, Federal Railroad Administration, Federal Transit Administration, or Federal Aviation Administration shall use the ''split sample'' method of collection for those employees.

(ii) Employers using the split sample method of collection shall follow the procedures in this paragraph (f)(10)(ii):

(A) The donor shall urinate into a collection container or a specimen bottle capable of holding at least 60 ml.

(B)(*1*) If a collection container is used, the collection site person, in the presence of the donor, pours the urine into two specimen bottles. Thirty (30) ml shall be poured into one specimen bottle, to be used as the primary specimen. At least 15 ml shall be poured into the other bottle, to be used as the split specimen.

(*2*) If a single specimen bottle is used as a collection container, the collection site person, in the presence of the donor, shall pour 15 ml of urine from the specimen bottle into a second specimen bottle (to be used as the split specimen) and retain the remainder (at least 30 ml) in the collection bottle (to be used as the primary specimen).

(C) Nothing in this section precludes the use of a collection method or system that does not involve the physical pouring of urine from one container or bottle to another by the collection site person, provided that the method or system results in the subdivision of the specimen into a primary (30 ml) and a split (at least 15 ml) specimen that can be transmitted to the laboratory and tested in accordance with the requirements of this Subpart.

(D) Both bottles shall be shipped in a single shipping container, together with copies 1,2, and the split specimen copy of the chain of custody form, to the laboratory.

(E) If the test result of the primary specimen is positive, the employee may request that the MRO direct that the split specimen be tested in a different DHHS-certified laboratory for presence of the drug(s) for which a positive result was obtained in the test of the primary specimen. The MRO shall honor such a request if it is made within 72 hours of the employee having been notified of a verified positive test result.

(F) When the MRO informs the laboratory in writing that the employee has requested a test of the split specimen, the laboratory shall forward, to a different DHHS-approved laboratory, the split specimen bottle, with seal intact, a copy of the MRO request, and the split specimen copy of the chain of custody form with appropriate chain of custody entries.

(G) The result of the test of the split specimen is transmitted by the second laboratory to the MRO.

(H) Action required by DOT agency regulations as the result of a positive drug test (e.g., removal from performing a safety-sensitive function) is not stayed pending the result of the test of the split specimen.

(I) If the result of the test of the split specimen fails to reconfirm the presence of the drug(s) or drug metabolite(s) found in the primary specimen, the MRO shall cancel the test, and report the cancellation and the reasons for it to the DOT, the employer, and the employee.

(iii) Employers using the single sample collection method shall follow the procedures in paragraph:

(A) The collector may choose to direct the employee to urinate either directly into a specimen bottle or into a separate collection container.

(B) If a separate collection container is used, the collection site person shall pour at least 30 ml of the urine from the collection container into the specimen bottle in the presence of the employee.

(iv)(A)(*1*) In either collection methodology, upon receiving the specimen from the individual, the collection site person shall determine if the specimen has at least 30 milliliters of urine for a single specimen collection or 45 milliliters of urine for a split specimen collection.

(*2*) If the individual has not provided the required quantity of urine, the specimen shall be discarded. The collection site person shall direct the individual to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a new urine specimen, whichever occurs first. If the employee refuses to drink fluids as directed or to provide a new urine specimen, the collection site person shall terminate the collection and notify the employer that the employee has refused to submit to testing.

(*3*) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, the collection site person shall discontinue the collection and notify the employer.

(B) The employer shall direct any employee who does not provide a sufficient urine specimen (see paragraph (f)(10)(iv)(A)(*3*) of this section) to obtain, as soon as possible after the attempted provision of urine, an evaluation from a licensed physician who is acceptable to the employer concerning the employee's ability to provide an adequate amount of urine.

(*1*) If the physician determines, in his or her reasonable medical judgment, that a medical condition has, or with a high degree of probability, could have, precluded the employee from providing an adequate amount of urine, the employee's failure to provide an adequate amount of urine shall not be deemed a refusal to take a test. For purposes of this paragraph, a medical condition includes an ascertainable physiological condition (e.g., a urinary system dysfunction) or a documented pre-existing psychological disorder, but does not include unsupported assertions of ''situational anxiety'' or dehydration. The physician shall provide to the MRO a brief written statement setting forth his or her conclusion and the basis for it, which shall not include detailed information on the medical condition of the employee. Upon receipt of this statement, the MRO shall report his or her conclusions to the employer in writing.

(*2*) If the physician, in his or her reasonable medical judgment, is unable to make the determination set forth in paragraph (f)(10)(iv)(B)(*1*) of this section, the employee's failure to provide an adequate amount of urine shall be regarded as a refusal to take a test. The physician shall provide to the MRO a brief written statement setting forth his or her conclusion and the basis for it, which shall not include detailed information on the medical condition of the employee. Upon receipt of this statement, the MRO shall report his or her conclusions to the employer in writing.

(11) After the specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measure is critical and in no case shall exceed 4 minutes.

(13) A specimen temperature outside the range of 32°–38° C/90°–100° F constitutes a reason to believe that the individual has altered or substituted the specimen (see paragraph (e)(2)(i) of this section). In such cases, the individual supplying the specimen may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen.

(14) Immediately after the specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted on the urine custody and control form.

(15) All specimens suspected of being adulterated shall be forwarded to the laboratory for testing.

(16) Whenever there is reason to believe that a particular individual has altered or substituted the specimen as described in paragraph (e)(2) (i) or (iii) of this section, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person.

(17) Both the individual being tested and the collection site person shall

keep the specimen in view at all times prior to its being sealed and labeled. As provided below, the specimen shall be sealed (by placement of a tamperproof seal over the bottle cap and down the sides of the bottle) and labeled in the presence of the employee. If the specimen is transferred to a second bottle, the collection site person shall request the individual to observe the transfer of the specimen and the placement of the tamperproof seal over the bottle cap and down the sides of the bottle.

(18) The collection site person and the individual being tested shall be present at the same time during procedures outlined in paragraphs (f)(19)–(f)(22) of this section.

(19) The collection site person shall place securely on the bottle an identification label which contains the date, the individual's specimen number, and any other identifying information provided or required by the employer. If separate from the label, the tamperproof seal shall also be applied.

(20) The individual shall initial the identification label on the specimen bottle for the purpose of certifying that it is the specimen collected from him or her.

(21) The collection site person shall enter on the drug testing custody and control form all information identifying the specimen. The collection site person shall sign the drug testing custody and control form certifying that the collection was accomplished according to the applicable Federal requirements.

(22)(i) The individual shall be asked to read and sign a statement on the drug testing custody and control form certifying that the specimen identified as having been collected from him or her is in fact the specimen he or she provided.

(ii) When specified by DOT agency regulation or required by the collection site (other than an employer site) or by the laboratory, the employee may be required to sign a consent or release form authorizing the collection of the specimen, analysis of the specimen for designated controlled substances, and release of the results to the employer. The employee may not be required to waive liability with respect to negligence on the part of any person participating in the collection, handling or analysis of the specimen or to indemnify any person for the negligence of others.

(23) The collection site person shall complete the chain of custody portion of the drug testing custody and control form to indicate receipt of the specimen from the employee and shall certify proper completion of the collection.

(24) The urine specimen and chain of custody form are now ready for shipment. If the specimen is not immediately prepared for shipment, the collection site person shall ensure that it is appropriately safeguarded during temporary storage.

(25)(i) While any part of the above chain of custody procedures is being performed, it is essential that the urine specimen and custody documents be under the control of the involved collection site person. If the involved collection site person leaves his or her work station momentarily, the collection site person shall take the specimen and drug testing custody and control form with him or her or shall secure them. After the collection site person returns to the work station, the custody process will continue. If the collection site person is leaving for an extended period of time, he or she shall package the specimen for mailing before leaving the site.

(ii) The collection site person shall not leave the collection site in the interval between presentation of the specimen by the employee and securement of the sample with an identifying label bearing the employee's specimen identification number (shown on the urine custody and control form) and seal initialed by the employee. If it becomes necessary for the collection site person to leave the site during this interval, the collection shall be nullified and (at the election of the employer) a new collection begun.

(g) *Collection control.* To the maximum extent possible, collection site personnel shall keep the individual's specimen bottle within sight both before and after the individual has urinated. After the specimen is collected, it shall be properly sealed and labeled.

(h) *Transportation to laboratory*. Collection site personnel shall arrange to

ship the collected specimen to the drug testing laboratory. The specimens shall be placed in shipping containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes and/or padded mailers); and those containers shall be securely sealed to eliminate the possibility of undetected tampering with the specimen and/or the form. On the tape sealing the shipping container, the collection site person shall sign and enter the date specimens were sealed in the shipping container for shipment. The collection site person shall ensure that the chain of custody documentation is enclosed in each container sealed for shipment to the drug testing laboratory. Since specimens and documentation are sealed in shipping containers that would indicate any tampering during transit to the laboratory and couriers, express carriers, and postal service personnel do not have access to the chain of custody forms, there is no requirement that such personnel document chain of custody for the shipping container during transit. Nor is there a requirement that there be a chain of custody entry when a specimen which is sealed in such a shipping container is put into or taken out of secure storage at the collection site prior to pickup by such personnel. This means that the chain of custody is not broken, and a test shall not be canceled, because couriers, express carriers, postal service personnel, or similar persons involved solely with the transportation of a specimen to a laboratory, have not documented their participation in the chain of custody documentation or because the chain of custody does not contain entries related to putting the specimen into or removing it from secure temporary storage at the collection site.

(i) *Failure to cooperate.* If the employee refuses to cooperate with the collection process, the collection site person shall inform the employer representative and shall document the non-cooperation on the drug testing custody and control form.

(j) *Employee requiring medical attention.* If the sample is being collected from an employee in need of medical attention (e.g., as part of a post-accident test given in an emergency medical facility), necessary medical attention shall not be delayed in order to collect the specimen.

(k) *Use of chain of custody form.* A chain of custody form (and a laboratory internal chain of custody document, where applicable), shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on the form each time a specimen is handled or transferred and every individual in the chain of custody shall be identified. Since specimens and documentation are sealed in shipping containers that would indicate any tampering during transit to the laboratory and couriers, express carriers, and postal service personnel do not have access to the chain of custody forms, there is no requirement that such personnel document chain of custody for the shipping container during transit. Nor is there a requirement that there be a chain of custody entry when a specimen which is sealed in such a shipping container is put into or taken out of secure storage at the collection site prior to pickup by such personnel. This means that the chain of custody is not broken, and a test shall not be canceled, because couriers, express carriers, postal service personnel, or similar persons involved solely with the transportation of a specimen to a laboratory, have not documented their participation in the chain of custody documentation or because the chain of custody does not contain entries related to putting the specimen into or removing it from secure temporary storage at the collection site. Every effort shall be made to minimize the number of persons handling specimens.

[54 FR 49866, Dec. 1, 1989, as amended at 59 FR 7355, Feb. 15, 1994; 59 FR 43000, Aug. 19, 1994; 61 FR 37699, July 19, 1996]

§40.27 Laboratory personnel.

(a) *Day-to-day management.* (1) The laboratory shall have a qualified individual to assume professional, organizational, educational, and administrative responsibility for the laboratory's urine drug testing facility.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by a State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in paragraph (a)(2) (i), (ii), or (iii) of this section, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse, and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the drug testing laboratory even where another individual has overall responsibility for an entire multi-specialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible individual whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in § 40.29(n)(1).)

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the tests results provided are accurate and reliable.

(b) *Test validation.* The laboratory's urine drug testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate more than one person to perform this function. This individual(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

(c) *Day-to-day operations and supervision of analysts.* The laboratory's urine drug testing facility shall have an individual to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the

procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) *Other personnel.* Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) *Training.* The laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* Laboratory personnel files shall include: resume of training and experience, certification or license if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

§40.29 Laboratory analysis procedures.

(a) *Security and chain of custody.* (1) Drug testing laboratories shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory process or to areas where records are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of Federal agencies for which the laboratory is engaged in urine testing or on behalf of DHHS, all authorized visitors and maintenance and service personnel shall be escorted at all times. Documentation of individuals accessing these areas, dates, and time of entry and purpose of entry must be maintained.

(2) Laboratories shall use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

(b) *Receiving.* (1)(i) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and the employer's chain of custody forms attached to the shipment shall be immediately reported to the employer and shall be noted on the laboratory's chain of custody form which shall accompany the specimens while they are in the laboratory's possession.

(ii) Where the employer has used the split sample method, and the laboratory observes that the split specimen is untestable, inadequate, or unavailable for testing, the laboratory shall nevertheless test the primary specimen. The laboratory does not inform the MRO or the employer of the untestability, inadequacy, or unavailability of the split specimen until and unless the primary specimen is a verified positive test and the MRO has informed the laboratory that the employee has requested a test of the split specimen.

(2) In situations where the employer uses the split sample collection method, the laboratory shall log in the split specimen, with the split specimen bottle seal remaining intact. The laboratory shall store this sample securely (see paragraph (c) of this section). If the result of the test of the primary specimen is negative, the laboratory may discard the split specimen. If the result of the test of the primary specimen is positive, the laboratory shall retain the split specimen in frozen storage for 60 days from the date on which the laboratory acquires it (see

paragraph (h) of this section). Following the end of the 60-day period, if not informed by the MRO that the employee has requested a test of the split specimen, the laboratory may discard the split specimen.

(3) When directed in writing by the MRO to forward the split specimen to another DHHS-certified laboratory for analysis, the second laboratory shall analyze the split specimen by GC/MS to reconfirm the presence of the drug(s) or drug metabolite(s) found in the primary specimen. Such GC/MS confirmation shall be conducted without regard to the cutoff levels of §40.29(f). The split specimen shall be retained in long-term storage for one year by the laboratory conducting the analysis of the split specimen (or longer if litigation concerning the test is pending).

(c) *Short-term refrigerated storage.* Specimens that do not receive an initial test within 7 days of arrival at the laboratory shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. Emergency power equipment shall be available in case of prolonged power failure.

(d) *Specimen processing.* Laboratory facilities for urine drug testing will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts.

(e) *Initial test.* (1) The initial test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these five drugs or classes of drugs:

	Initial test cutoff levels (ng/ml)
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites	*300
Phencyclidine	25
Amphetamines	1,000

*–25 ng/ml if immunoassay specific for free morphine.

(2) These cutoff levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations.

(f) *Confirmatory test.* (1) All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cutoff levels listed in this paragraph for each drug. All confirmations shall be by quantitative analysis. Concentrations that exceed the linear region of the standard curve shall be documented in the laboratory record as ''greater than highest standard curve value.''

	Confirmatory test cutoff levels (ng/ml)
Marijuana metabolite [1]	15
Cocaine metabolite [2]	150
Opiates	
Morphine	300
Codeine	300
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine [3]	500

[1] Delta-9-tetrahydrocannabinol-9-carboxylic acid.
[2] Benzoylecgonine.
[3] Specimen must also contain amphetamine at a concentration greater than or equal to 200 ng/ml.

(2) These cutoff levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations.

(g) *Reporting results.* (1) The laboratory shall report test results to the employer's Medical Review Officer within an average of 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual. The report shall identify the drugs/metabolites tested for, whether positive or negative, the specimen number assigned by the employer,

and the drug testing laboratory specimen identification number (accession number).

(2) The laboratory shall report as negative all specimens that are negative on the initial test or negative on the confirmatory test. Only specimens confirmed positive shall be reported positive for a specific drug.

(3) The Medical Review Officer may request from the laboratory and the laboratory shall provide quantitation of test results. The MRO shall report whether the test is positive or negative, and may report the drug(s) for which there was a positive test, but shall not disclose the quantitation of test results to the employer. *Provided,* that the MRO may reveal the quantitation of a positive test result to the employer, the employee, or the decision-maker in a lawsuit, grievance, or other proceeding initiated by or on behalf of the employee and arising from a verified positive drug test.

(4) The laboratory may transmit results to the Medical Review Officer by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The laboratory and employer must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the Medical Review Officer the original or a certified true copy of the drug testing custody and control form (part 2), which, in the case of a report positive for drug use, shall be signed (after the required certification block) by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports, and attached to which shall be a copy of the test report.

(6) The laboratory shall provide the employer an aggregate quarterly statistical summary of urinalysis testing of the employer's employees. Laboratories may provide the report to a consortium provided that the laboratory provides employer-specific data and the consortium forwards the employer-specific data to the respective employers within 14 days of receipt of the laboratory report. The laboratory shall provide the report to the employer or consortium not more than 14 calendar days after the end of the quarter covered by the summary. Laboratory confirmation data only shall be included from test results reported within that quarter. The summary shall contain only the following information:

(i) Number of specimens received for testing;

(ii) Number of specimens confirmed positive for—

(A) Marijuana metabolite

(B) Cocaine metabolite

(C) Opiates;

(D) Phencyclidine;

(E) Amphetamines;

(iii) Number of specimens for which a test was not performed.

Quarterly reports shall not contain personal identifying information or other data from which it is reasonably likely that information about individuals' tests can be readily inferred. If necessary, in order to prevent disclosure of such data, the laboratory shall not send such a report until data are sufficiently aggregated to make such an inference unlikely. In any quarter in which a report is withheld for this reason, or because no testing was conducted, the laboratory shall so inform the consortium/employer in writing.

(7) The laboratory shall make available copies of all analytical results for employer drug testing programs when requested by DOT or any DOT agency with regulatory authority over the employer.

(8) Unless otherwise instructed by the employer in writing, all records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

(h) *Long-term storage.* Long-term frozen storage (−20°C or less) ensures that positive urine specimens will be available for any necessary retest during administrative or disciplinary proceedings. Drug testing laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive, in their original labeled specimen bottles. Within this 1-year period, an employer (or other person designated in a DOT agency regulation) may request

the laboratory to retain the specimen for an additional period of time, but if no such request is received the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens known to be under legal challenge for an indefinite period.

(i) *Retesting specimens.* Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cutoff requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(j) *Subcontracting.* Drug testing laboratories shall not subcontract and shall perform all work with their own personnel and equipment. The laboratory must be capable of performing testing for the five classes of drugs (marijuana, cocaine, opiates, phencyclidine and amphetamines) using the initial immunoassay and confirmatory GC/MS methods specified in this part. This paragraph does not prohibit subcontracting of laboratory analysis if specimens are sent directly from the collection site to the subcontractor, the subcontractor is a laboratory certified by DHHS as required in this part, the subcontractor performs all analysis and provides storage required under this part, and the subcontractor is responsible to the employer for compliance with this part and applicable DOT agency regulations as if it were the prime contractor.

(k) *Laboratory facilities.* (1) Laboratory facilities shall comply with applicable provisions of any State licensing requirements.

(2) Laboratories certified in accordance with DHHS Guidelines shall have the capability, at the same laboratory premises, of performing initial and confirmatory tests for each drug or metabolite for which service is offered.

(l) *Inspections.* The Secretary, a DOT agency, any employer utilizing the laboratory, DHHS or any organization performing laboratory certification on behalf of DHHS reserves the right to inspect the laboratory at any time. Employer contracts with laboratories for drug testing, as well as contracts for collection site services, shall permit the employer and the DOT agency of jurisdiction (directly or through an agent) to conduct unannounced inspections.

(m) *Documentation.* The drug testing laboratories shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2 year period may be extended upon written notification by a DOT agency or by any employer for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The laboratory shall maintain documents for any specimen known to be under legal challenge for an indefinite period.

(n) *Additional requirements for certified laboratories.*—(1) *Procedure manual.* Each laboratory shall have a procedure manual which includes the principles of each test preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of methods, cutoff values, mechanisms for reporting results, controls criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) *Standards and controls.* Laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date.

(3) *Instruments and equipment.* (i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall

be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks and instructions for major trouble shooting and repair. Records shall be available on preventive maintenance.

(4) *Remedial actions.* There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) *Personnel available to testify at proceedings.* A laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against an employee when that proceeding is based on positive urinalysis results reported by the laboratory.

(6) The laboratory shall not enter into any relationship with an employer's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having an employer use a specific MRO.

[54 FR 49866, Dec. 1, 1989, as amended at 59 FR 7356, Feb. 15, 1994; 59 FR 43001, Aug. 19, 1994]

§ 40.31 Quality assurance and quality control.

(a) *General.* Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody security and reporting of results, initial and confirmatory testing and validation of analytical procedures. Quality assurance procedures shall be designed, implemented and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) *Laboratory quality control requirements for initial tests.* Each analytical run of specimens to be screened shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the cutoff level.

In addition, with each batch of samples a sufficient number of standards shall be included to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Implementation of procedures to ensure the carryover does not contaminate the testing of an individual's specimen shall be documented. A minimum of 10 percent of all test samples shall be quality control specimens. Laboratory quality control samples, prepared from spiked urine samples of determined concentration shall be included in the run and should appear as normal samples to laboratory analysts. One percent of each run, with a minimum of at least one sample, shall be the laboratory's own quality control samples.

(c) *Laboratory quality control requirements for confirmation tests.* Each analytical run of specimens to be confirmed shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the cutoff level. The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(d) *Employer blind performance test procedures.* (1) Each employer covered by DOT agency drug testing regulations shall use blind testing quality control procedures as provided in this paragraph.

(2) Each employer shall submit three blind performance test specimens for each 100 employee specimens it submits, up to a maximum of 100 blind performance test specimens submitted per quarter. A DOT agency may increase this per quarter maximum number of

samples if doing so is necessary to ensure adequate quality control of employers or consortiums with very large numbers of employees.

(3) For employers with 2000 or more covered employees, approximately 80 percent of the blind performance test samples shall be blank (i.e., containing no drug or otherwise as approved by a DOT agency) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the employer is testing. This paragraph shall not be construed to prohibit spiking of other (potentially interfering) compounds, as technically appropriate, in order to verify the specificity of a particular assay.

(4) Employers with fewer than 2000 covered employees may submit blind performance test specimens as provided in paragraph (d)(3) of this section. Such employers may also submit only blank samples or may submit two separately labeled portions of a specimen from the same non-covered employee.

(5) Consortiums shall be responsible for the submission of blind samples on behalf of their members. The blind sampling rate shall apply to the total number of samples submitted by the consortium.

(6) The DOT agency concerned shall investigate, or shall refer to DHHS for investigation, any unsatisfactory performance testing result and, based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be made of the investigative findings and the corrective action taken by the laboratory, and that record shall be dated and signed by the individual responsible for the day-to-day management and operation of the drug testing laboratory. Then the DOT agency shall send the document to the employer as a report of the unsatisfactory performance testing incident. The DOT agency shall ensure notification of the finding to DHHS.

(7) Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the employer shall promptly notify the DOT agency concerned. The DOT agency and the employer shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future, and, if there is reason to believe the error could have been systemic, the DOT agency may also require review and reanalysis of previously run specimens.

(8) Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the employer shall instruct the laboratory to submit all quality control data from the batch of specimens which included the false positive specimen to the DOT agency concerned. In addition, the laboratory shall retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's urine drug testing. The DOT agency concerned may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the DOT agency, DHHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

§ 40.33 Reporting and review of results.

(a) *Medical review officer shall review confirmed positive results.* (1) An essential part of the drug testing program is the final review of confirmed positive results from the laboratory. A positive test result does not automatically identify an employee/applicant as having used drugs in violation of a DOT agency regulation. An individual with a detailed knowledge of possible alternate medical explanations is essential

to the review of results. This review shall be performed by the Medical Review Officer (MRO) prior to the transmission of the results to employer administrative officials. The MRO review shall include review of the chain of custody to ensure that it is complete and sufficient on its face.

(2) The duties of the MRO with respect to negative results are purely administrative.

(b) *Medical review officer—qualifications and responsibilities.* (1) The MRO shall be a licensed physician with knowledge of substance abuse disorders and may be an employee of a transportation employer or a private physician retained for this purpose.

(2) [Reserved]

(3) The role of the MRO is to review and interpret confirmed positive test results obtained through the employer's testing program. In carrying out this responsibility, the MRO shall examine alternate medical explanations for any positive test result. This action may include conducting a medical interview and review of the individual's medical history, or review of any other relevant biomedical factors. The MRO shall review all medical records made available by the tested individual when a confirmed positive test could have resulted from legally prescribed medication. The MRO shall not, however, consider the results or urine samples that are not obtained or processed in accordance with this part.

(c) *Positive test result.* (1) Prior to making a final decision to verify a positive test result for an individual, the MRO shall give the individual an opportunity to discuss the test result with him or her.

(2) The MRO shall contact the individual directly, on a confidential basis, to determine whether the employee wishes to discuss the test result. A staff person under the MRO's supervision may make the initial contact, and a medically licensed or certified staff person may gather information from the employee. Except as provided in paragraph (c)(5) of this section, the MRO shall talk directly with the employee before verifying a test as positive.

(3) If, after making all reasonable efforts and documenting them, the MRO is unable to reach the individual directly, the MRO shall contact a designated management official who shall direct the individual to contact the MRO as soon as possible. If it becomes necessary to reach the individual through the designated management official, the designated management official shall employ procedures that ensure, to the maximum extent practicable, the requirement that the employee contact the MRO is held in confidence.

(4) If, after making all reasonable efforts, the designated management official is unable to contact the employee, the employer may place the employee on temporary medically unqualified status or medical leave.

(5) The MRO may verify a test as positive without having communicated directly with the employee about the test in three circumstances:

(i) The employee expressly declines the opportunity to discuss the test;

(ii) Neither the MRO nor the designated employer representative, after making all reasonable efforts, has been able to contact the employee within 14 days of the date on which the MRO receives the confirmed positive test result from the laboratory;

(iii) The designated employer representative has successfully made and documented a contact with the employee and instructed the employee to contact the MRO (see paragraphs (c)(3) and (c)(4) of this section), and more than five days have passed since the date the employee was successfully contacted by the designated employer representative.

(6) If a test is verified positive under the circumstances specified in paragraph (c)(5) (ii) or (iii) of this section, the employee may present to the MRO information documenting that serious illness, injury, or other circumstances unavoidably prevented the employee from being contacted by the MRO or designated employer representative (paragraph (c)(5)(ii) of this section) or from contacting the MRO (paragraph (c)(5)(iii) of this section) within the times provided. The MRO, on the basis of such information, may reopen the verification, allowing the employee to present information concerning a legitimate explanation for the confirmed

positive test. If the MRO concludes that there is a legitimate explanation, the MRO declares the test to be negative.

(7) Following verification of a positive test result, the MRO shall, as provided in the employer's policy, refer the case to the employer's employee assistance or rehabilitation program, if applicable, to the management official empowered to recommend or take administrative action (or the official's designated agent), or both.

(d) *Verification for opiates; review for prescription medication.* Before the MRO verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test—of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). (This requirement does not apply if the employer's GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine.)

(e) In a situation in which the employer has used the single sample method of collection, the MRO shall notify each employee who has a confirmed positive test that the employee has 72 hours in which to request a reanalysis of the original specimen, if the test is verified positive. If requested to do so by the employee within 72 hours of the employee's having been informed of a verified positive test, the Medical Review Officer shall direct, in writing, a reanalysis of the original sample. The MRO may also direct, in writing, such a reanalysis if the MRO questions the accuracy or validity of any test result. Only the MRO may authorize such a reanalysis, and such a reanalysis may take place only at laboratories certified by DHHS. If the reanalysis fails to reconfirm the presence of the drug or drug metabolite, the MRO shall cancel the test and report the cancellation and the reasons for it to the DOT, the employer and the employee.

(f)(1) In situations in which the employer uses the split sample method of collection, the MRO shall notify each employee who has a confirmed positive test that the employee has 72 hours in which to request a test of the split specimen, if the test is verified as positive. If the employee requests an analysis of the split specimen within 72 hours of having been informed of a verified positive test, the MRO shall direct, in writing, the laboratory to provide the split specimen to another DHHS-certified laboratory for analysis. If the analysis of the split specimen fails to reconfirm the presence of the drug(s) or drug metabolite(s) found in the primary specimen, or if the split specimen is unavailable, inadequate for testing or untestable, the MRO shall cancel the test and report cancellation and the reasons for it to the DOT, the employer, and the employee.

(2) If the analysis of the split specimen is reconfirmed by the second laboratory for the presence of the drug(s) or drug metabolites(s), the MRO shall notify the employer and employee of the results of the test.

(g) If an employee has not contacted the MRO within 72 hours, as provided in paragraphs (e) and (f) of this section, the employee may present to the MRO information documenting that serious illness, injury, inability to contact the MRO, lack of actual notice of the verified positive test, or other circumstances unavoidably prevented the employee from timely contacting the MRO. If the MRO concludes that there is a legitimate explanation for the employee's failure to contact the MRO within 72 hours, the MRO shall direct that the reanalysis of the primary specimen or analysis of the split specimen, as applicable, be performed.

(h) When the employer uses the split sample method of collection, the employee is not authorized to request a reanalysis of the primary specimen as provided in paragraph (e) of this section.

(i) *Disclosure of information.* Except as provided in this paragraph, the MRO shall not disclose to any third party medical information provided by the individual to the MRO as a part of the testing verification process.

(1) The MRO may disclose such information to the employer, a DOT agency or other Federal safety agency, or a physician responsible for determining the medical qualification of the employee under an applicable DOT agency regulation, as applicable, only if—

(i) An applicable DOT regulation permits or requires such disclosure;

(ii) In the MRO's reasonable medical judgment, the information could result in the employee being determined to be medically unqualified under an applicable DOT agency rule; or

(iii) In the MRO's reasonable medical judgment, in a situation in which there is no DOT agency rule establishing physical qualification standards applicable to the employee, the information indicates that continued performance by the employee of his or her safety-sensitive function could pose a significant safety risk.

(2) Before obtaining medical information from the employee as part of the verification process, the MRO shall inform the employee that information may be disclosed to third parties as provided in this paragraph and the identity of any parties to whom information may be disclosed.

[54 FR 49866, Dec. 1, 1989, as amended at 59 FR 7356, Feb. 15, 1994; 61 FR 37699, July 19, 1996]

§40.35 Protection of employee records.

Employer contracts with laboratories shall require that the laboratory maintain employee test records in confidence, as provided in DOT agency regulations. The contracts shall provide that the laboratory shall disclose information related to a positive drug test of an individual to the individual, the employer, or the decisionmaker in a lawsuit, grievance, or other proceeding initiated by or on behalf of the individual and arising from a certified positive drug test.

§40.37 Individual access to test and laboratory certification results.

Any employee who is the subject of a drug test conducted under this part shall, upon written request, have access to any records relating to his or her drug test and any records relating to the results of any relevant certification, review, or revocation-of-certification proceedings.

§40.39 Use of certified laboratories.

(a) Except as provided in paragraph (b) of this section, employers subject to this part shall use only laboratories certified under the DHHS ''Mandatory Guidelines for Federal Workplace Drug Testing Programs,'' April 11, 1988, and subsequent amendments thereto.

(b) Employers subject to this part may also use laboratories located outside the United States if—

(1) The Department of Transportation, based on a written recommendation from DHHS, has certified the laboratory as meeting DHHS laboratory certification standards or deemed the laboratory fully equivalent to a laboratory meeting DHHS laboratory certification standards; or

(2) The Department of Transportation, based on a written recommendation from DHHS, has recognized a foreign certifying organization as having equivalent laboratory certification standards and procedures to those of DHHS, and the foreign certifying organization has certified the laboratory, pursuant to those equivalent standards and procedures.

[61 FR 37016, July 16, 1996]

Subpart C—Alcohol Testing

SOURCE: 59 FR 7357, Feb. 15, 1994, unless otherwise noted.

§40.51 The breath alcohol technician.

(a) The breath alcohol technician (BAT) shall be trained to proficiency in the operation of the EBT he or she is using and in the alcohol testing procedures of this part.

(1) Proficiency shall be demonstrated by successful completion of a course of instruction which, at a minimum, provides training in the principles of EBT methodology, operation, and calibration checks; the fundamentals of breath analysis for alcohol content; and the procedures required in this part for obtaining a breath sample, and interpreting and recording EBT results.

(2) Only courses of instruction for operation of EBTs that are equivalent to the Department of Transportation model course, as determined by the National Highway Traffic Safety Administration (NHTSA), may be used to train BATs to proficiency. On request, NHTSA will review a BAT instruction course for equivalency.

(3) The course of instruction shall provide documentation that the BAT

has demonstrated competence in the operation of the specific EBT(s) he/she will use.

(4) Any BAT who will perform an external calibration check of an EBT shall be trained to proficiency in conducting the check on the particular model of EBT, to include practical experience and demonstrated competence in preparing the breath alcohol simulator or alcohol standard, and in maintenance and calibration of the EBT.

(5) The BAT shall receive additional training, as needed, to ensure proficiency, concerning new or additional devices or changes in technology that he or she will use.

(6) The employer or its agent shall establish documentation of the training and proficiency test of each BAT it uses to test employees, and maintain the documentation as provided in § 40.83.

(b) A BAT-qualified supervisor of an employee may conduct the alcohol test for that employee only if another BAT is unavailable to perform the test in a timely manner. A supervisor shall not serve as a BAT for the employee in any circumstance prohibited by a DOT operating administration regulation.

(c) Law enforcement officers who have been certified by state or local governments to conduct breath alcohol testing are deemed to be qualified as BATs. In order for a test conducted by such an officer to be accepted under Department of Transportation alcohol testing requirements, the officer must have been certified by a state or local government to use the EBT or non-evidential alcohol screening device that was used for the test.

[59 FR 7357, Feb. 15, 1994, as amended at 60 FR 19679, Apr. 20, 1995]

§ 40.53 Devices to be used for breath alcohol tests.

(a) For screening tests, employers shall use only EBTs. When the employer uses for a screening test an EBT that does not meet the requirements of paragraphs (b) (1) through (3) of this section, the employer shall use a log book in conjunction with the EBT (see § 40.59(c)).

(b) For confirmation tests, employers shall use EBTs that meet the following requirements:

(1) EBTs shall have the capability of providing, independently or by direct link to a separate printer, a printed result in triplicate (or three consecutive identical copies) of each breath test and of the operations specified in paragraphs (b) (2) and (3) of this section.

(2) EBTs shall be capable of assigning a unique and sequential number to each completed test, with the number capable of being read by the BAT and the employee before each test and being printed out on each copy of the result.

(3) EBTs shall be capable of printing out, on each copy of the result, the manufacturer's name for the device, the device's serial number, and the time of the test.

(4) EBTs shall be able to distinguish alcohol from acetone at the 0.02 alcohol concentration level.

(5) EBTs shall be capable of the following operations:

(i) Testing an air blank prior to each collection of breath; and

(ii) Performing an external calibration check.

§ 40.55 Quality assurance plans for EBTs.

(a) In order to be used in either screening or confirmation alcohol testing subject to this part, an EBT shall have a quality assurance plan (QAP) developed by the manufacturer.

(1) The plan shall designate the method or methods to be used to perform external calibration checks of the device, using only calibration devices on the NHTSA ''Conforming Products List of Calibrating Units for Breath Alcohol Tests.''

(2) The plan shall specify the minimum intervals for performing external calibration checks of the device. Intervals shall be specified for different frequencies of use, environmental conditions (*e.g.*, temperature, altitude, humidity), and contexts of operation (*e.g.*, stationary or mobile use).

(3) The plan shall specify the tolerances on an external calibration check within which the EBT is regarded to be in proper calibration.

(4) The plan shall specify inspection, maintenance, and calibration requirements and intervals for the device.

(5) For a plan to be regarded as valid, the manufacturer shall have submitted the plan to NHTSA for review and have received NHTSA approval of the plan.

(b) The employer shall comply with the NHTSA-approved quality assurance plan for each EBT it uses for alcohol screening or confirmation testing subject to this part.

(1) The employer shall ensure that external calibration checks of each EBT are performed as provided in the QAP.

(2) The employer shall take an EBT out of service if any external calibration check results in a reading outside the tolerances for the EBT set forth in the QAP. The EBT shall not again be used for alcohol testing under this part until it has been serviced and has had an external calibration check resulting in a reading within the tolerances for the EBT.

(3) The employer shall ensure that inspection, maintenance, and calibration of each EBT are performed by the manufacturer or a maintenance representative certified by the device's manufacturer or a state health agency or other appropriate state agency. The employer shall also ensure that each BAT or other individual who performs an external calibration check of an EBT used for alcohol testing subject to this part has demonstrated proficiency in conducting such a check of the model of EBT in question.

(4) The employer shall maintain records of the external calibration checks of EBTs as provided in §40.83.

(c) When the employer is not using the EBT at an alcohol testing site, the employer shall store the EBT in a secure space.

§40.57 Locations for breath alcohol testing.

(a) Each employer shall conduct alcohol testing in a location that affords visual and aural privacy to the individual being tested, sufficient to prevent unauthorized persons from seeing or hearing test results. All necessary equipment, personnel, and materials for breath testing shall be provided at the location where testing is conducted.

(b) An employer may use a mobile collection facility (*e.g.*, a van equipped for alcohol testing) that meets the requirements of paragraph (a) of this section.

(c) No unauthorized persons shall be permitted access to the testing location when the EBT remains unsecured or, in order to prevent such persons from seeing or hearing a testing result, at any time when testing is being conducted.

(d) In unusual circumstances (*e.g.*, when it is essential to conduct a test outdoors at the scene of an accident), a test may be conducted at a location that does not fully meet the requirements of paragraph (a) of this section. In such a case, the employer or BAT shall provide visual and aural privacy to the employee to the greatest extent practicable.

(e) The BAT shall supervise only one employee's use of the EBT at a time. The BAT shall not leave the alcohol testing location while the testing procedure for a given employee (see §§40.61 through 40.65) is in progress.

§40.59 The breath alcohol testing form.

(a) Each employer shall use the breath alcohol testing form prescribed under this part. The form is found in appendix A to this subpart. Employers may not modify or revise this form, except that a form directly generated by an EBT may omit the space for affixing a separate printed result to the form.

(b) The form shall provide triplicate (or three consecutive identical) copies. Copy 1 (white) shall be transmitted to the employer. Copy 2 (green) shall be provided to the employee. Copy 3 (blue) shall be retained by the BAT. Except for a form generated by an EBT, the form shall be 8½ by 11 inches in size.

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

§40.61 Preparation for breath alcohol testing.

(a) When the employee enters the alcohol testing location, the BAT will require him or her to provide positive identification (*e.g.*, through use of a photo I.D. card or identification by an employer representative). On request by the employee, the BAT shall provide positive identification to the employee.

(b) The BAT shall explain the testing procedure to the employee.

§ 40.63 Procedures for screening tests.

(a) The BAT shall complete Step 1 on the Breath Alcohol Testing Form. The employee shall then complete Step 2 on the form, signing the certification. Refusal by the employee to sign this certification shall be regarded as a refusal to take the test.

(b) An individually-sealed mouthpiece shall be opened in view of the employee and BAT and attached to the EBT in accordance with the manufacturer's instructions.

(c) The BAT shall instruct the employee to blow forcefully into the mouthpiece for at least 6 seconds or until the EBT indicates that an adequate amount of breath has been obtained.

(d)(1) If the EBT does not meet the requirements of §40.53(b) (1) through (3), the BAT shall ensure, before a screening test is administered to each employee, that he or she and the employee read the sequential test number displayed on the EBT. The BAT shall record the displayed result, test number, testing device, serial number of the testing device, and time in Step # of the form.

(2) If the EBT does not meet the requirements of §40.53(b)(1) through (3), the BAT and the employee shall take the following steps:

(i) Show the employee the result displayed on the EBT. The BAT shall record the displayed result, test number, testing device, serial number of the testing device, time and quantified result in Step 3 of the form.

(ii) Record the test number, date of the test, name of the BAT, location, and quantified test result in the log book. The employee shall initial the log book entry.

(3) If the EBT provides a printed result, but does not print the results directly onto the form, the BAT shall show the employee the result displayed on the EBT. The BAT shall then affix the test result printout to the breath alcohol test form in the designated space, using a method that will provide clear evidence of removal (*e.g.*, tamper-evident tape).

(4) If the EBT prints the test results directly onto the form, the BAT shall show the employee the result displayed on the EBT.

(e)(1) In any case in which the result of the screening test is a breath alcohol concentration of less than 0.02, the BAT shall date the form and sign the certification in Step 3 of the form. The employee shall sign the certification and fill in the date in Step 4 of the form.

(2) No further testing is authorized. The BAT shall transmit the result of less than 0.02 to the employer in a confidential manner, and the employer shall receive and store the information so as to ensure that confidentiality is maintained as required by §40.81.

(3) If the employee does not sign the certification in Step 4 of the form for a test, it shall not be considered a refusal to be tested. In this event, the BAT shall note the employee's failure to sign in the ''Remarks'' section of the form.

(4) If a test result printed by the EBT (see paragraph (d)(3) or (d)(4) of this section) does not match the displayed result, or if a sequential test number printed by the EBT does not match the sequential test number displayed by the EBT prior to the screening test (see paragraph (d)(1) of this section), the BAT shall note the disparity in the ''Remarks'' section. Both the employee and the BAT shall initial and sign the notation. In accordance with §40.79, the test is invalid and the employee shall be so advised.

(f) If the result of the screening test is an alcohol concentration of 0.02 or greater, a confirmation test shall be performed as provided in §40.65.

(g) If the confirmation test will be conducted by a different BAT, the BAT who conducts the screening test shall complete and sign the form and log book entry. The BAT will provide the employee with Copy 2 of the form.

(h) If the confirmation test will be conducted at a different site from the screening test, the employer or its agent shall ensure that—

(1) The employee is advised against taking any of the actions mentioned in the first sentence of §40.65(b) of this part;

(2) The employee is advised that he or she must not drive, perform safety-sensitive duties, or operate heavy equipment, as noted in Block 4 of the alcohol testing form; and

(3) The employee is under observation of a BAT, STT, or other employer personnel while in transit from the screening test site to the confirmation test site.

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

§40.65 Procedures for confirmation tests.

(a) If a BAT other than the one who conducted the screening test is conducting the confirmation test, the new BAT shall follow the procedures of §40.61.

(b) The BAT shall instruct the employee not to eat, drink, put any object or substance in his or her mouth, and, to the extent possible, not belch during a waiting period before the confirmation test. This time period begins with the completion of the screening test, and shall not be less than 15 minutes. The confirmation test shall be conducted within 30 minutes of the completion of the screening test. The BAT shall explain to the employee the reason for this requirement (*i.e.,* to prevent any accumulation of mouth alcohol leading to an artificially high reading) and the fact that it is for the employee's benefit. The BAT shall also explain that the test will be conducted at the end of the waiting period, even if the employee has disregarded the instruction. If the BAT becomes aware that the employee has not complied with this instruction, the BAT shall so note in the ''Remarks'' section of the form. If the BAT conducts the confirmation test more than 30 minutes after the result of the screening test has been obtained, the BAT shall note in the ''Remarks'' section of the form the time that elapsed between the screening and confirmation tests and the reason why the confirmation test could not be conducted within 30 minutes of the screening test.

(c)(1) If a BAT other than the one who conducted the screening test is conducting the confirmation test, the new BAT shall initiate a new Breath Alcohol Testing form. The BAT shall complete Step 1 on the form. The employee shall then complete Step 2 on the form, signing the certification. Refusal by the employee to sign this certification shall be regarded as a refusal to take the test. The BAT shall note in the ''Remarks'' section of the form that a different BAT conducted the screening test.

(2) In all cases, the procedures of §40.63 (a), (b), and (c) shall be followed. A new mouthpiece shall be used for the confirmation test.

(d) Before the confirmation test is administered for each employee, the BAT shall ensure that the EBT registers 0.00 on an air blank. If the reading is greater than 0.00, the BAT shall conduct one more air blank. If the reading is greater than 0.00, testing shall not proceed using that instrument, which shall be taken out of service. However, testing may proceed on another instrument. Any EBT taken out of service because of failure to perform an air blank accurately shall not be used for testing until a check of external calibration is completed and the EBT is found to be within tolerance limits.

(e) Before the confirmation test is administered for each employee, the BAT shall ensure that he or she and the employee read the sequential test number displayed by the EBT.

(f) In the event that the screening and confirmation test results are not identical, the confirmation test result is deemed to be the final result upon which any action under operating administration rules shall be based.

(g)(1) If the EBT provides a printed result, but does not print the results directly onto the form, the BAT shall show the employee the result displayed on the EBT. The BAT shall then affix the test result printout to the breath alcohol test form in the designated space, using a method that will provide clear evidence of removal (*e.g.,* tamper-evident tape).

(2) If the EBT prints the test results directly onto the form, the BAT shall show the employee the result displayed on the EBT.

(h)(1) Following the completion of the test, the BAT shall date the form and sign the certification in Step 3 of

the form. The employee shall sign the certification and fill in the date in Step 4 of the form.

(2) If the employee does not sign the certification in Step 4 of the form, it shall not be considered a refusal to be tested. In this event, the BAT shall note the employee's failure to sign in the ''Remarks'' section.

(3) If a test result printed by the EBT (see paragraph (g)(1) or (g)(2) of this section) does not match the displayed result, or if a sequential test number printed by the EBT does not match the sequential test number displayed by the EBT prior to the confirmation test (see paragraph (e) of this section), the BAT shall note the disparity in the ''Remarks'' section. Both the employee and the BAT shall initial and sign the notation. In accordance with §40.79, the test is invalid and the employee shall be so advised.

(i) The BAT shall transmit all results to the employer in a confidential manner.

(1) Each employer shall designate one or more employer representatives for the purpose of receiving and handling alcohol testing results in a confidential manner. All communications by BATs to the employer concerning the alcohol testing results of employees shall be to a designated employer representative.

(2) Such transmission may be in writing (the employer copy (Copy 1) of the breath alcohol testing form), in person or by telephone or electronic means, but the BAT shall ensure immediate transmission to the employer of results that require the employer to prevent the employee from performing a safety-sensitive function.

(3) If the initial transmission is not in writing (e.g., by telephone), the employer shall establish a mechanism to verify the identity of the BAT providing the information.

(4) If the initial transmission is not in writing, the BAT shall follow the initial transmission by providing to the employer the employer's copy of the breath alcohol testing form. The employer shall store the information so as to ensure that confidentiality is maintained as required by §40.81.

[59 FR 7357, Feb. 15, 1994, as amended at 59 FR 43002, Aug. 19, 1994; 60 FR 19679, Apr. 20, 1995]

§40.67 Refusals to test and uncompleted tests.

(a) Refusal by an employee to complete and sign the breath alcohol testing form (Step 2), to provide breath, to provide an adequate amount of breath, or otherwise to cooperate with the testing process in a way that prevents the completion of the test, shall be noted by the BAT in the remarks section of the form. The testing process shall be terminated and the BAT shall immediately notify the employer.

(b) If a screening or confirmation test cannot be completed, or if an event occurs that would invalidate the test, the BAT shall, if practicable, begin a new screening or confirmation test, as applicable, using a new breath alcohol testing form with a new sequential test number (in the case of a screening test conducted on an EBT that meets the requirements of §40.53(b) or in the case of a confirmation test).

§40.69 Inability to provide an adequate amount of breath.

(a) This section sets forth procedures to be followed in any case in which an employee is unable, or alleges that he or she is unable, to provide an amount of breath sufficient to permit a valid breath test because of a medical condition.

(b) The BAT shall again instruct the employee to attempt to provide an adequate amount of breath. If the employee refuses to make the attempt, the BAT shall immediately inform the employer.

(c) If the employee attempts and fails to provide an adequate amount of breath, the BAT shall so note in the ''Remarks'' section of the breath alcohol testing form and immediately inform the employer.

(d) If the employee attempts and fails to provide an adequate amount of breath, the employer shall proceed as follows:

(1) [Reserved]

(2) The employer shall direct the employee to obtain, as soon as practical after the attempted provision of breath, an evaluation from a licensed physician who is acceptable to the employer concerning the employee's medical ability to provide an adequate amount of breath.

(i) If the physician determines, in his or her reasonable medical judgment, that a medical condition has, or with a high degree of probability, could have, precluded the employee from providing an adequate amount of breath, the employee's failure to provide an adequate amount of breath shall not be deemed a refusal to take a test. The physician shall provide to the employer a written statement of the basis for his or her conclusion.

(ii) If the licensed physician, in his or her reasonable medical judgment, is unable to make the determination set forth in paragraph (d)(2)(i) of this section the employee's failure to provide an adequate amount of breath shall be regarded as a refusal to take a test. The licensed physician shall provide a written statement of the basis for his or her conclusion to the employer.

§§40.71–40.77 [Reserved]

§40.79 Invalid tests.

(a) A breath alcohol test shall be invalid under the following circumstances:

(1) The next external calibration check of an EBT produces a result that differs by more than the tolerance stated in the QAP from the known value of the test standard. In this event, every test result of 0.02 or above obtained on the device since the last valid external calibration check shall be invalid;

(2) The BAT does not observe the minimum 15-minute waiting period prior to the confirmation test, as provided in §40.65(b);

(3) The BAT does not perform an air blank of the EBT before a confirmation test, or an air blank does not result in a reading of 0.00 prior to the administration of the test, as provided in §40.65;

(4) The BAT does not sign the form as required by §§40.63 and 40.65;

(5) The BAT has failed to note on the remarks section of the form that the employee has failed or refused to sign the form following the recording or printing on or attachment to the form of the test result;

(6) An EBT fails to print a confirmation test result; or

(7) On a confirmation test and, where applicable, on a screening test, the sequential test number or alcohol concentration displayed on the EBT is not the same as the sequential test number or alcohol concentration on the printed result.

(b) [Reserved]

[59 FR 7357, Feb. 15, 1994, as amended at 59 FR 43002, Aug. 19, 1994]

§40.81 Availability and disclosure of alcohol testing information about individual employees.

(a) Employers shall maintain records in a secure manner, so that disclosure of information to unauthorized persons does not occur.

(b) Except as required by law or expressly authorized or required in this section, no employer shall release covered employee information that is contained in the records required to be maintained by this part or by DOT agency alcohol misuse rules.

(c) An employee subject to testing is entitled, upon written request, to obtain copies of any records pertaining to the employee's use of alcohol, including any records pertaining to his or her alcohol tests. The employer shall promptly provide the records requested by the employee. Access to an employee's records shall not be contingent upon payment for records other than those specifically requested.

(d) Each employer shall permit access to all facilities utilized in complying with the requirements of this part and DOT agency alcohol misuse rules to the Secretary of Transportation, any DOT agency with regulatory authority over the employer, or a state agency with regulatory authority over the employer (as authorized by DOT agency regulations).

(e) When requested by the Secretary of Transportation, any DOT agency with regulatory authority over the employer, or a state agency with regulatory authority over the employer (as authorized by DOT agency regulations), each employer shall make available copies of all results for employer alcohol testing conducted under the requirements of this part and any other information pertaining to the employer's alcohol misuse prevention program. The information shall include name-specific alcohol test results, records and reports.

(f) When requested by the National Transportation Safety Board as part of an accident investigation, an employer shall disclose information related to the employer's administration of any post-accident alcohol tests administered following the accident under investigation.

(g) An employer shall make records available to a subsequent employer upon receipt of a written request from a covered employee. Disclosure by the subsequent employer is permitted only as expressly authorized by the terms of the employee's written request.

(h) An employer may disclose information required to be maintained under this part pertaining to a covered employee to that employee or to the decisionmaker in a lawsuit, grievance, or other proceeding initiated by or on behalf of the individual, and arising from the results of an alcohol test administered under the requirements of this part, or from the employer's determination that the employee engaged in conduct prohibited by a DOT agency alcohol misuse regulation (including, but not limited to, a worker's compensation, unemployment compensation, or other proceeding relating to a benefit sought by the employee).

(i) An employer shall release information regarding a covered employee's records as directed by the specific, written consent of the employee authorizing release of the information to an identified person. Release of such information is permitted only in accordance with the terms of the employee's consent.

§ 40.83 Maintenance and disclosure of records concerning EBTs and BATs.

(a) Each employer or its agent shall maintain the following records for two years:

(1) Records of the inspection and maintenance of each EBT used in employee testing;

(2) Documentation of the employer's compliance with the QAP for each EBT it uses for alcohol testing under this part;

(3) Records of the training and proficiency testing of each BAT used in employee testing;

(4) The log books required by § 40.59(c).

(b) Each employer or its agent shall maintain for five years records pertaining to the calibration of each EBT used in alcohol testing under this part, including records of the results of external calibration checks.

(c) Records required to be maintained by this section shall be disclosed on the same basis as provided in § 40.81.

Subpart D—Non-Evidential Alcohol Screening Devices

SOURCE: 60 FR 19679, Apr. 20, 1995, unless otherwise noted.

§ 40.91 Authorization for use of non-evidential alcohol screening devices.

Non-evidential alcohol screening tests, performed using screening devices included by the National Highway Traffic Safety Administration on its conforming products list for non-evidential screening devices, may be used in lieu of EBTs to perform screening tests required by operating administrations' alcohol testing regulations. Non-evidential screening devices may not be used for confirmation alcohol tests, which must be conducted using EBTs as provided in subpart C of this part.

§ 40.93 The screening test technician.

(a) Anyone meeting the requirements of this part to be a BAT may act as a screening test technician (STT), provided that the individual has demonstrated proficiency in the operation of the non-evidential screening device he or she is using.

(b) Any other individual may act as an STT if he or she successfully completes a course of instruction concerning the procedures required by this part for conducting alcohol screening tests. Only the Department of Transportation model course, or a course of instruction determined by the Department of Transportation's Office of Drug Enforcement and Program Compliance to be equivalent to it, may be used for this purpose.

(c) With respect to any non-evidential screening device involving changes, contrasts, or other readings that are indicated on the device in terms of color, STTs shall, in order to be regarded as proficient, be able to

discern correctly these changes, contrasts or readings.

(d) The STT shall receive additional training, as needed, to ensure proficiency, concerning new or additional devices or changes in technology that he or she will use.

(e) The employer or its agent shall document the training and proficiency of each STT it uses to test employees and maintain the documentation as provided in §40.83.

(f) The provisions of §40.51(b) and (c); §40.57; §40.59; §40.61; §40.63 (e)(1)–(2), (f), (g), and (h); §40.69; and §40.81; and other provisions, as applicable, of this part apply to STTs as well as to BATs.

§40.95 Quality assurance plans for non-evidential screening devices.

(a) In order to be used for alcohol screening tests subject to this part, a non-evidential screening device shall have an approved quality assurance plan (QAP) developed by the manufacturer and approved by the National Highway Traffic Safety Administration (NHTSA).

(1) The plan shall designate the method or methods to be used to perform quality control checks; the temperatures at which the non-evidential screening device shall be stored and used, as well as other environmental conditions (*e.g.*, altitude, humidity) that may affect the performance of the device; and, where relevant, the shelf life of the device.

(2) The QAP shall prohibit the use of any device that does not pass the specified quality control checks or that has passed its expiration date.

(b) The manufacturers' instructions on or included in the package for each saliva testing device shall include directions on the proper use of the device, the time frame within which the device must be read and the manner in which the reading is made.

(c) The employer and its agents shall comply with the QAP and manufacturer's instructions for each non-evidential screening device it uses for alcohol screening tests subject to this Part.

§40.97 Locations for non-evidential alcohol screening tests.

(a) Locations for non-evidential alcohol screening tests shall meet the same requirements set forth for breath alcohol testing in §40.57 of this part.

(b) The STT shall supervise only one employee's use of a non-evidential screening device at a time. The STT shall not leave the alcohol testing location while the screening test procedure for a given employee is in progress.

§40.99 Testing forms.

STTs conducting tests using a non-evidential screening device shall use the alcohol testing form as provided in §40.59 and appendix B of this part for the screening test.

§40.101 Screening test procedure.

(a) The steps for preparation for testing shall be the same as provided for breath alcohol testing in §40.61 of this part.

(b) The STT shall complete Step 1 on the form required by §40.99. The employee shall then complete Step 2 on the form, signing the certification. Refusal by the employee to sign this certification shall be regarded as a refusal to take the test.

(c) If the employer is using a non-evidential breath testing device, the STT shall follow the same steps outlined for screening tests using EBTs in §40.63.

(d) If the employer is using a saliva testing device, the STT shall take the following steps:

(1) The STT shall explain the testing procedure to the employee.

(2) The STT shall check the expiration date of the saliva testing device, show the date to the employee, and shall not use a device at any time subsequent to the expiration date.

(3) The STT shall open an individually sealed package containing the device in the presence of the employee.

(4) The STT shall offer the employee the opportunity to use the swab. If the employee chooses to use the swab, the STT shall instruct the employee to insert the absorbent end of the swab into the employee's mouth, moving it actively throughout the mouth for a sufficient time to ensure that it is completely saturated, as provided in the manufacturer's instructions for the device.

(5) If the employee chooses not to use the swab, or in all cases in which a new test is necessary because the device did

not activate (see paragraph (d)(8) of this section), the STT shall insert the absorbent end of the swab into the employee's mouth, moving it actively throughout the mouth for a sufficient time to ensure that it is completely saturated, as provided in the manufacturer's instructions for the device. The STT shall wear a surgical grade glove while doing so.

(6) The STT shall place the device on a flat surface or otherwise in a position in which the swab can be firmly placed into the opening provided in the device for this purpose. The STT shall insert the swab into this opening and maintain firm pressure on the device until the device indicates that it is activated.

(7) If the procedures of paragraph (d)(3)–(d)(5) of this section are not followed successfully (e.g., the swab breaks, the STT drops the swab on the floor or another surface, the swab is removed or falls from the device before the device is activated), the STT shall discard the device and swab and conduct a new test using a new device. The new device shall be one that has been under the control of the employer or STT prior to the test. The STT shall note in the remarks section of the form the reason for the new test. In this case, the STT shall offer the employee the choice of using the swab himself or herself or having the STT use the swab. If the procedures of paragraph (d)(3)–(d)(5) of this section are not followed successfully on the new test, the collection shall be terminated and an explanation provided in the remarks section of the form. A new test shall then be conducted, using an EBT for both the screening and confirmation tests.

(8) If the procedures of paragraph (d)(3)–(d)(5) of this section are followed successfully, but the device is not activated, the STT shall discard the device and swab and conduct a new test, in the same manner as provided in paragraph (d)(7) of this section. In this case, the STT shall place the swab into the employee's mouth to collect saliva for the new test.

(9) The STT shall read the result displayed on the device two minutes after inserting the swab into the device. The STT shall show the device and its reading to the employee and enter the result on the form.

(10) Devices, swabs, gloves and other materials used in saliva testing shall not be reused, and shall be disposed of in a sanitary manner following their use, consistent with applicable requirements.

(e) In the case of any screening test performed under this section, the STT, after determining the alcohol concentration result, shall follow the applicable provisions of §40.63 (e)(1)–(2), (f), (g), and (h). The STT shall also enter, in the ''Remarks'' section of the form, a notation that the screening test was performed using a non-evidential breath testing device or a saliva device, as applicable. Following completion of the screening test, the STT shall date the form and sign the certification in Step 3 of the form.

§40.103 Refusals to test and uncompleted tests.

(a) Refusal by an employee to complete and sign the alcohol testing form required by §40.99 (Step 2), to provide a breath or saliva sample, to provide an adequate amount of breath, or otherwise to cooperate in a way that prevents the completion of the testing process, shall be noted by the STT in the remarks section of the form. This constitutes a refusal to test. The testing process shall be terminated and the STT shall immediately notify the employer.

(b) If the screening test cannot be completed, for reasons other than a refusal by the employee, or if an event occurs that would invalidate the test, the STT shall, if practicable, immediately begin a new screening test, using a new testing form and, in the case of a test using a saliva screening device, a new device.

§40.105 Inability to provide an adequate amount of breath or saliva.

(a) If an employee is unable to provide sufficient breath to complete a test on a non-evidential breath testing device, the procedures of §40.69 apply.

(b) If an employee is unable to provide sufficient saliva to complete a test on a saliva screening device (e.g., the employee does not provide sufficient saliva to activate the device), the STT,

as provided in §40.101 of this part, shall conduct a new test using a new device. If the employee refuses to complete the new test, the STT shall terminate testing and immediately inform the employer. This constitutes a refusal to test.

(c) If the new test is completed, but there is an insufficient amount of saliva to activate the device, STT shall immediately inform the employer, which shall immediately cause an alcohol test to be administered to the employee using an EBT.

§40.107 Invalid tests.

An alcohol test using a non-evidential screening device shall be invalid under the following circumstances:

(a) With respect to a test conducted on a saliva device—

(1) The result is read before two minutes or after 15 minutes from the time the swab is inserted into the device;

(2) The device does not activate;

(3) The device is used for a test after the expiration date printed on its package; or

(4) The STT fails to note in the remarks section of the form that the screening test was conducted using a saliva device;

(b) With respect to a test conducted on any non-evidential alcohol testing device, the STT has failed to note on the remarks section of the form that the employee has failed or refused to sign the form following the recording on the form of the test result.

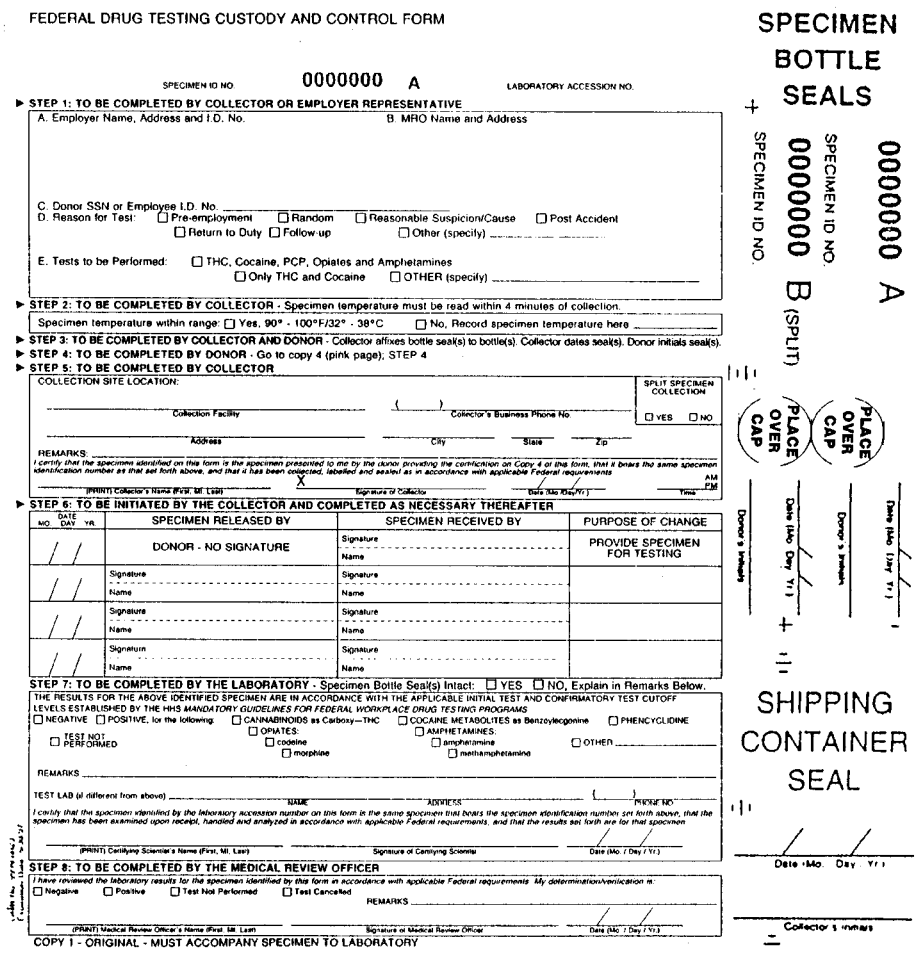
§40.109 Availability and disclosure of alcohol testing information about individual employees.

The provisions of §40.81 apply to records of non-evidential alcohol screening tests.

§ 40.111 Maintenance and disclosure of records concerning non-evidential testing devices and STTs.

Records concerning STTs and non-evidential testing devices shall be maintained and disclosed following the same requirements applicable to BATs and EBTs under § 40.81 of this part.

APPENDIX A TO PART 40—FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM



FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. 0000000 A LABORATORY ACCESSION NO.

▶ STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No. B. MRO Name and Address

C. Donor SSN or Employee I.D. No.

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify)

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines ☐ Only THC and Cocaine ☐ OTHER (specify)

▶ STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here

▶ STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

▶ STEP 4: TO BE COMPLETED BY DONOR - Go to copy 4 (pink page); STEP 4

▶ STEP 5: TO BE COMPLETED BY COLLECTOR

COLLECTION SITE LOCATION:

Collection Facility ( ) Collector's Business Phone No.

SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

Address City State Zip

REMARKS

I certify that the specimens identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements

(PRINT) Collector's Name (First, MI, Last) X Signature of Collector Date (Mo./Day/Yr.) / / Time AM PM

▶ STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature / Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature / Name	Signature / Name	
/ /	Signature / Name	Signature / Name	
/ /	Signature / Name	Signature / Name	

STEP 7: TO BE COMPLETED BY THE LABORATORY - Specimen Bottle Seal(s) Intact: ☐ YES ☐ NO, Explain in Remarks Below.

THE RESULTS FOR THE ABOVE IDENTIFIED SPECIMEN ARE IN ACCORDANCE WITH THE APPLICABLE INITIAL TEST AND CONFIRMATORY TEST CUTOFF LEVELS ESTABLISHED BY THE HHS *MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS*

☐ NEGATIVE ☐ POSITIVE, for the following: ☐ CANNABINOIDS as Carboxy—THC ☐ COCAINE METABOLITES as Benzoylecgonine ☐ PHENCYCLIDINE ☐ OPIATES: ☐ codeine ☐ morphine ☐ AMPHETAMINES: ☐ amphetamine ☐ methamphetamine ☐ OTHER ☐ TEST NOT PERFORMED

REMARKS

TEST LAB (if different from above) NAME ADDRESS ( ) PHONE NO.

I certify that the specimen identified by the laboratory accession number on this form is the same specimen that bears the specimen identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results set forth are for that specimen

(PRINT) Certifying Scientist's Name (First, MI, Last) Signature of Certifying Scientist Date (Mo. / Day / Yr.) / /

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☐ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled

REMARKS

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo. / Day / Yr.) / /

COPY 1 - ORIGINAL - MUST ACCOMPANY SPECIMEN TO LABORATORY

SPECIMEN BOTTLE SEALS

SPECIMEN ID NO. 0000000 A

SPECIMEN ID NO. 0000000 B (SPLIT)

PLACE OVER CAP

PLACE OVER CAP

Donor's Initials

Donor's Initials

Date (Mo. Day Yr.) / /

Date (Mo. Day Yr.) / /

SHIPPING CONTAINER SEAL

Date (Mo. Day Yr.) / /

Collector's Initials

Paperwork Reduction Act Notice (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information, including the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information is estimated for each respondent to average: 5 minutes/donor; 4 minutes/collector; 3 minutes/laboratory; and 3 minutes/Medical Review Officer. Federal employees may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to Public Health Service Reports Clearance Officer, Attn: PRA, Hubert H. Humphrey Building, Rm 721-B, 200 Independence Ave. S.W., Washington, D.C. 20201. Individuals from the private sector may send comments/suggestions to: Department of Transportation, Drug Enforcement and Program Compliance, Rm 9404, 400 Seventh St. S.W., Washington, D.C. 20590. In addition, copies of all comments/suggestions may be sent to: Office of Management and Budget, Paperwork Reduction Project, Rm 3001, 725 Seventeenth St. N.W., Washington, D.C. 20503.

Back of Copy 1, 2, 3, 4, and 6.

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. LABORATORY ACCESSION NO.

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No. B. MRO Name and Address

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident
☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines
☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

STEP 4: TO BE COMPLETED BY DONOR - Go to copy 4 (pink page); STEP 4

STEP 5: TO BE COMPLETED BY COLLECTOR

COLLECTION SITE LOCATION: SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

Collection Facility ( ) Collector's Business Phone No.

Address City State Zip

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(PRINT) Collector's Name (First, MI, Last) Signature of Collector Date (Mo./Day/Yr.) AM PM Time

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	

STEP 7: TO BE COMPLETED BY THE LABORATORY - Specimen Bottle Seal(s) Intact: ☐ YES ☐ NO, Explain in Remarks Below.

THE RESULTS FOR THE ABOVE IDENTIFIED SPECIMEN ARE IN ACCORDANCE WITH THE APPLICABLE INITIAL TEST AND CONFIRMATORY TEST CUTOFF LEVELS ESTABLISHED BY THE HHS *MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS*

☐ NEGATIVE ☐ POSITIVE, for the following: ☐ CANNABINOIDS as Carboxy—THC ☐ COCAINE METABOLITES as Benzoylecgonine ☐ PHENCYCLIDINE
☐ OPIATES: ☐ codeine ☐ morphine ☐ AMPHETAMINES: ☐ amphetamine ☐ methamphetamine ☐ OTHER _____
☐ TEST NOT PERFORMED

REMARKS _____

TEST LAB (if different from above) _____ ( ) _____
NAME ADDRESS PHONE NO.

I certify that the specimen identified by the laboratory accession number on this form is the same specimen that bears the specimen identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results set forth are for that specimen.

(PRINT) Certifying Scientist's Name (First, MI, Last) Signature of Certifying Scientist Date (Mo. / Day / Yr.)

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☐ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled

REMARKS _____

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo. / Day / Yr.)

COPY 2 - 2nd ORIGINAL - MUST ACCOMPANY SPECIMEN TO LABORATORY

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. -B LABORATORY ACCESSION NO.

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No. B. MRO Name and Address

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines ☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

STEP 4: TO BE COMPLETED BY DONOR - Go to copy 4 (pink page); STEP 4

STEP 5: TO BE COMPLETED BY COLLECTOR

COLLECTION SITE LOCATION:

SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

_____ ( ) _____
Collection Facility Collector's Business Phone No.

_____ _____ _____ _____
Address City State Zip

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

_____ _____ / / _____ AM PM
(PRINT) Collector's Name (First, MI, Last) Signature of Collector Date (Mo./Day/Yr.) Time

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	

STEP 7: TO BE COMPLETED BY THE LABORATORY - Specimen Bottle Seal(s) Intact: ☐ YES ☐ NO, Explain in Remarks Below.

THE RESULTS FOR THE ABOVE IDENTIFIED SPECIMEN ARE IN ACCORDANCE WITH THE APPLICABLE PROCEDURES ESTABLISHED BY THE HHS MANDATORY *GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS*

☐ RECONFIRMED for the following: ☐ CANNABINOIDS as Carboxy—THC ☐ COCAINE METABOLITES as Benzoylecgonine ☐ PHENCYCLIDINE
☐ FAILED TO RECONFIRM ☐ OPIATES: ☐ AMPHETAMINES:
☐ TEST NOT PERFORMED ☐ codeine ☐ amphetamine ☐ OTHER _____
☐ morphine ☐ methamphetamine

REMARKS _____

TEST LAB (if different from above) _____ ( )
NAME ADDRESS PHONE NO.

I certify that the specimen identified by the laboratory accession number on this form is the same specimen that bears the specimen identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results set forth are for that specimen.

_____ _____ / / /
(PRINT) Certifying Scientist's Name (First, MI, Last) Signature of Certifying Scientist Date (Mo. / Day / Yr.)

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☐ Reconfirmed ☐ Failed to reconfirm- Both tests cancelled ☐ Test not performed Both tests cancelled REMARKS _____

_____ _____ / / /
(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo. / Day / Yr.)

COPY 3 - SPLIT SPECIMEN MUST ACCOMPANY SPLIT SPECIMEN TO LABORATORY

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. LABORATORY ACCESSION NO.

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No. B. MRO Name and Address

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident
☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines
☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

▶ **STEP 4: SEE BELOW**

STEP 5: TO BE COMPLETED BY COLLECTOR - RETURN TO COPY 1

COLLECTION SITE LOCATION:

Collection Facility ( ) Collector's Business Phone No.

SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

Address City State Zip

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(PRINT) Collector's Name (First, MI, Last) Signature of Collector Date (Mo./Day/Yr.) Time AM PM

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	

▶ **STEP 4: TO BE COMPLETED BY DONOR**

Daytime Phone No. ( ) Evening Phone No. ( ) Date of Birth / / Mo. Day Yr.

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; that each specimen bottle used was sealed with a tamper-evident seal in my presence and that the information provided on this form and on the label affixed to each specimen bottle is correct.

(PRINT) Donor's Name (First, MI, Last) X Signature of Donor Date (Mo. / Day / Yr.)

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications as a "memory jogger." THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5).—DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☐ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled

REMARKS _____

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo. / Day / Yr.)

COPY 4 - SEND DIRECTLY TO MEDICAL REVIEW OFFICER - DO NOT SEND TO LABORATORY

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. LABORATORY ACCESSION NO.

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No. B. MRO Name and Address

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident
☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines
☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

STEP 4: SEE BELOW

STEP 5: TO BE COMPLETED BY COLLECTOR - RETURN TO COPY 1

COLLECTION SITE LOCATION:

Collection Facility ( ) Collector's Business Phone No.

SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

Address City State Zip

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(PRINT) Collector's Name (First, MI, Last) Signature of Collector Date (Mo./Day/Yr.) Time AM PM

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	

STEP 4: TO BE COMPLETED BY DONOR

Daytime Phone No. ( ) Evening Phone No. ( ) Date of Birth / / Mo. Day Yr.

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; that each specimen bottle used was sealed with a tamper-evident seal in my presence and that the information provided on this form and on the label affixed to each specimen bottle is correct.

(PRINT) Donor's Name (First, MI, Last) X Signature of Donor Date (Mo. / Day / Yr.)

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications as a "memory jogger." THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5).—DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☐ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled

REMARKS _____

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo. / Day / Yr.)

COPY 5 - GIVE TO DONOR DO NOT SEND TO LABORATORY

Privacy Act Statement: (For Federal Employees Only)

Submission of the information on the attached form is voluntary. However, incomplete submission of the information, refusal to provide a urine specimen, or substitution or adulteration of a specimen may result in delay or denial of your application for employment/appointment or may result in removal from the Federal service or other disciplinary action.

The authority for obtaining the urine specimen and identifying information contained herein is Executive Order 12564 ("Drug-Free Federal Workplace"), 5 U.S.C. § 3301 (2), 5 U.S.C. § 7301 and Section 503 of Public Law 100-71, 5 U.S.C. § 7301 note. Under provisions of Executive Order 12564 and 5 U.S.C. 7301, test results may only be disclosed to agency officials on a need-to-know basis. This may include the agency Medical Review Officer, the administrator of the Employee Assistance Program, and a supervisor with authority to take adverse personnel action. This information may also be disclosed to a court where necessary to defend against a challenge to an adverse personnel action.

Submission of your SSN is not required by law and is voluntary. Your refusal to furnish your number will not result in the denial of any right, benefit, or privilege provided by law. Your SSN is solicited, pursuant to Executive Order 9397, for purposes of associating information in agency files relating to you and for purposes of identifying the specimen provided for urinalysis testing for illegal drugs. If you refuse to indicate your SSN, a substitute number or other identifier will be assigned, as required, to process the specimen.

In the event laboratory analysis determines the presence of one or more illegal drugs in the specimen you provide, you will be contacted by an agency Medical Review Officer (MRO). The MRO will determine whether there is a legitimate medical explanation for the drug(s) identified by urinalysis.

Paperwork Reduction Act Notice (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information, including the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information is estimated for each respondent to average: 5 minutes/donor; 4 minutes/collector; 3 minutes/laboratory; and 3 minutes/Medical Review Officer. Federal employees may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to Public Health Service Reports Clearance Officer, Attn: PRA, Hubert H. Humphrey Building, Rm 721-B, 200 Independence Ave. S.W., Washington, D.C. 20201. Individuals from the private sector may send comments/suggestions to: Department of Transportation, Drug Enforcement and Program Compliance, Rm 9404, 400 Seventh St. S.W., Washington, D.C. 20590. In addition, copies of all comments/suggestions may be sent to: Office of Management and Budget, Paperwork Reduction Project, Rm 3001, 725 Seventeenth St. N.W., Washington, D.C. 20503.

Back of Copy 5.

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. LABORATORY ACCESSION NO.

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No. B. MRO Name and Address

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident
☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines
☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

STEP 4: SEE BELOW

STEP 5: TO BE COMPLETED BY COLLECTOR - RETURN TO COPY 1

COLLECTION SITE LOCATION:

Collection Facility ( ) Collector's Business Phone No.

SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

Address City State Zip

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(PRINT) Collector's Name (First, MI, Last) Signature of Collector Date (Mo./Day/Yr.) AM PM Time

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	

STEP 4: TO BE COMPLETED BY DONOR

Daytime Phone No. [redacted] Evening Phone No. [redacted] Date of Birth ___/___/___ Mo. Day Yr.

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; that each specimen bottle used was sealed with a tamper-evident seal in my presence and that the information provided on this form and on the label affixed to each specimen bottle is correct.

(PRINT) Donor's Name (First, MI, Last) Signature of Donor Date (Mo. / Day / Yr.)

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications as a "memory jogger." THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5).—DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☐ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled

REMARKS _____

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo. / Day / Yr.)

COPY 6 COLLECTOR RETAINS DO NOT SEND TO LABORATORY

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. LABORATORY ACCESSION NO.

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No. B. MRO Name and Address

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident
☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines
☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

STEP 4: SEE BELOW

STEP 5: TO BE COMPLETED BY COLLECTOR - RETURN TO COPY 1

COLLECTION SITE LOCATION:

Collection Facility ( ) Collector's Business Phone No.

SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

Address City State Zip

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(PRINT) Collector's Name (First, MI, Last) Signature of Collector Date (Mo./Day/Yr.) Time AM PM

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	

STEP 4: TO BE COMPLETED BY DONOR

Daytime Phone No. Evening Phone No. Date of Birth / / Mo. Day Yr.

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; that each specimen bottle used was sealed with a tamper-evident seal in my presence and that the information provided on this form and on the label affixed to each specimen bottle is correct.

(PRINT) Donor's Name (First, MI, Last) Signature of Donor Date (Mo. / Day / Yr.)

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications as a "memory jogger." THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5).—DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☐ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled

REMARKS _____

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo. / Day / Yr.)

COPY 7 FORWARD TO EMPLOYER - DO NOT SEND TO LABORATORY

INSTRUCTION FOR COMPLETING DRUG TESTING CUSTODY AND CONTROL FORM

The following instructions are in accordance with procedures established by the Department of Health and Human Services and the Department of Transportation mandatory guidelines for federal and transportation workplace drug testing programs.

NOTE: Use ballpoint pen, press hard, and check all copies for legibility.

STEP 1.

If the information in STEP 1 has not been completed, collector (not donor) completes STEP 1 (A-E).

NOTE: Donor refusal to provide SSN or Employee I.D. number must be annotated in STEP 5, collector's REMARKS section.

STEP 2.

Upon receiving specimen from donor, check specimen temperature. This must be accomplished within 4 minutes.

Check block marked "Yes" if temperature is within range.

If specimen temperature is not within range, check block marked "No" and record specimen temperature.

STEP 3. FOR SPLIT SPECIMEN COLLECTIONS ONLY

Secure caps on both specimen bottles and affix specimen bottle seal labeled A over the cap and down the sides of the primary specimen (bottle containing at least 30ml of urine).

Affix specimen bottle seal labeled B (split) on the split specimen (bottle containing at least 15ml of urine) in the same manner.

Record date on both specimen bottle seals.

FOR SINGLE SPECIMEN COLLECTION ONLY

Secure cap on specimen bottle (containing at least 30ml of urine) and affix specimen bottle seal labeled A over the cap and down the sides of the specimen bottle.

Record date on specimen bottle seal.

Instruct donor to initial the specimen bottle seal.

STEP 4.

Turn to Copy 4 (pink page). STEP 4.

Instruct donor to complete STEP 4.

Ensure donor provides his/her daytime and evening phone number and date of birth.

Instruct donor to read certification statement. Ensure donor prints his/her name and signs and dates the certification statement.

NOTE: Donor refusal to sign must be annotated in STEP 5, collector's remarks section.

Upon completion, check donor entries, return to Copy 1.

STEP 5.

After returning to Copy 1, go to STEP 5.

Complete the name and address of the facility at which the collection is taking place.

List a business telephone number where collector can be reached.

Place a check in the box indicating whether or not a split specimen was collected.

Record any unusual occurrences concerning the collection (e.g. donor refusal to provide information/sign certification statement, specimen collected under direct observation, suspected adulteration) in the remarks section.

Collector completes collection certification section by printing and signing his/her name, recording the date and time of collection. Be sure to circle A.M. or P.M.

STEP 6. CHAIN OF CUSTODY SECTION

NOTE: Each time the specimen is handled, transferred, or placed into storage prior to being packaged for shipment, every individual must be identified (including a direct observer, if required) and the date and purpose of change recorded. The following instructions pertain to a collection in which the donor provides a specimen directly to the collector who seals, packages, and ships the specimen to the laboratory.

Record date of collection.

In the "Specimen Received By" column, sign and print your name indicating that you have received the specimen from the donor.

The "Purpose of Change" entry in the next column is pre-printed (Provide Specimen for Testing) and explains the transfer of the specimen from the donor to the collector.

On the next line, record the date the specimen was released by you.

Complete the "Specimen Released By" block by signing and printing your name.

If you are preparing the specimen for shipment to the laboratory complete the "Specimen Received By" block by printing the carrier or shipment provider name only. (See Example)

Complete the "Purpose of Change" block explaining the transfer of the specimen from the collector to the carrier or shipment provider (e.g. Ship Specimen to Lab).

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
8 / 15 / 94	DONOR - NO SIGNATURE	Signature Connie Collector Name Connie Collector	PROVIDE SPECIMEN FOR TESTING
8 / 15 / 94	Signature Connie Collector Name Connie Collector	Signature ABC Courier Service Name	SHIP SPECIMEN TO LAB
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	

COMPLETING THE COLLECTION PROCESS

Upon completing Step 6, give donor his/her copy. Copy 5, (green page) of the Drug Testing Custody and Control Form.

Donor may leave the collection site at this point.

If a split specimen collection was performed, place both specimen bottles and Copies 1, 2, and 3 of the Drug Testing Custody and Control Form in the shipping container.

If a single collection was performed, place the specimen bottle and Copies 1 and 2 of the Drug Testing Custody and Control Form in the shipping container. Discard Copy 3.

Secure the shipping container. On the shipping container seal, record your initials and the date.

Send Copy 4 (pink page) directly to the Medical Review Officer. Do not send to laboratory.

Retain Copy 6 (yellow page) for your records.

Forward Copy 7 (blue page) to the employer. Do not send to laboratory.

[59 FR 43002, Aug. 19, 1994, as amended at 60 FR 19537, Apr. 19, 1995]

APPENDIX B TO PART 40—THE BREATH ALCOHOL TESTING FORM

U.S. Department of Transportation (DOT)
Breath Alcohol Testing Form

[THE INSTRUCTIONS FOR COMPLETING THIS FORM ARE ON THE BACK OF COPY 3]

▸ **STEP 1: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN**

A. Employee Name _____
(PRINT) (First, M.I., Last)

B. SSN or Employee ID No. _____

C. Employer Name, Address, & Telephone No. _____

_____

_____ ( )
Telephone Number

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post-accident ☐ Return to Duty ☐ Follow-up

▸ **STEP 2: TO BE COMPLETED BY EMPLOYEE**

I certify that I am about to submit to breath alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on this form is true and correct.

_____ Date ___/___/___
Signature of Employee Month Day Year

▸ **STEP 3: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN**

I certify that I have conducted breath alcohol testing on the above named individual in accordance with the procedures established in the U.S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing devices identified, and that the results are as recorded.

Screening test: Complete **only** if the testing device is not designed to **print** the following.

Test No.	Testing Device Name	Testing Device Serial Number	Time	AM PM	Result

Confirmation test: Confirmation test results MUST be affixed to the back of each copy of this form.

Remarks: _____

_____

_____

_____ _____ Date ___/___/___
(PRINT) Breath Alcohol Technician's Name (First, M.I., Last) Signature of Breath Alcohol Technician Month Day Year

▸ **STEP 4: TO BE COMPLETED BY EMPLOYEE**

*I certify that I have submitted to the breath alcohol test the results of which are accurately recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment if the results are **0.02 or greater**.*

_____ Date ___/___/___
Signature of Employee Month Day Year

COPY 1 - ORIGINAL - FORWARD TO THE EMPLOYER

OMB No. 2105-0529
Exp. Date: 2/28/97

AFFIX SCREENING TEST RESULTS HERE (IF APPLICABLE) USE TAMPER-EVIDENT TAPE	AFFIX CONFIRMATION TEST RESULTS HERE USE TAMPER-EVIDENT TAPE

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information is estimated for each respondent to average: 1 minute/employee, 4 minutes/Breath Alcohol Technician. Individuals may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to U.S. Department of Transportation, Drug Enforcement and Program Compliance, Room 9404, 400 Seventh St., SW, Washington, D.C. 20590 or Office of Management and Budget, Paperwork Reduction Project, Room 3001, 725 Seventeenth St., NW, Washington, D.C. 20503.

COPY 1 - ORIGINAL - FORWARD TO THE EMPLOYER

OMB No. 2105-0529
Exp. Date: 2/28/97

U.S. Department of Transportation (DOT)
Breath Alcohol Testing Form

[THE INSTRUCTIONS FOR COMPLETING THIS FORM ARE ON THE BACK OF COPY 3]

▸ **STEP 1: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN**

A. Employee Name _____
(PRINT) (First, M.I., Last)

B. SSN or Employee ID No. _____

C. Employer Name, _____
Address, & _____
Telephone No. _____

_____ ( ) _____
Telephone Number

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post-accident ☐ Return to Duty ☐ Follow-up

▸ **STEP 2: TO BE COMPLETED BY EMPLOYEE**

I certify that I am about to submit to breath alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on this form is true and correct.

_____ Date ___/___/___
Signature of Employee Month Day Year

▸ **STEP 3: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN**

I certify that I have conducted breath alcohol testing on the above named individual in accordance with the procedures established in the U.S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing devices identified, and that the results are as recorded.

Screening test: Complete only if the testing device is not designed to print the following.

Test No.	Testing Device Name	Testing Device Serial Number	Time	AM PM	Result

Confirmation test: Confirmation test results MUST be affixed to the back of each copy of this form.

Remarks: _____

_____ _____ Date ___/___/___
(PRINT) Breath Alcohol Technician's Name (First, M.I., Last) Signature of Breath Alcohol Technician Month Day Year

▸ **STEP 4: TO BE COMPLETED BY EMPLOYEE**

*I certify that I have submitted to the breath alcohol test the results of which are accurately recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment if the results are **0.02** or greater.*

_____ Date ___/___/___
Signature of Employee Month Day Year

COPY 2 - EMPLOYEE RETAINS

OMB No. 2105-0529
Exp. Date: 2/28/97

AFFIX SCREENING TEST RESULTS HERE (IF APPLICABLE)	AFFIX CONFIRMATION TEST RESULTS HERE
USE TAMPER-EVIDENT TAPE	USE TAMPER-EVIDENT TAPE

Privacy Act Statement

(applicable in those cases where completed Breath Alcohol Testing Forms are retained in a Federal Privacy Act system of records)

Except for your Social Security Number (SSN), submission of the information on the front side of this form is mandatory. Incomplete submission of the information, failure to provide an adequate breath specimen for testing without a valid medical explanation, engaging in conduct that clearly obstructs the testing process, or failure to sign the certification statements on the front side of this form may result in delay or denial of your application for employment/appointment, your inability to resume performing safety-sensitive duties, removal from a safety-sensitive position, or other disciplinary action.

The authority for obtaining the breath specimen required by the U.S. Department of Transportation is the Omnibus Transportation Employee Testing Act of 1991, Pub. L. 102-143, Title V. The principal purpose for which the information sought is to be used is to ensure that you have submitted to breath alcohol testing and to ensure that you are promptly notified in the event of noncompliance with the U.S. Department of Transportation breath alcohol testing requirements.

Submission of your SSN is not required by law and is voluntary. If you object to the use of your SSN in this form, you will not be denied any right, benefit, or privilege provided by law; a substitute number or other identifier will be assigned.

The information provided in this form may be disclosed, as a routine use, to a Federal, State, or local agency for authorized investigative or enforcement purposes or to a court or an administrative tribunal when the Government or one of its agencies is a party to a judicial proceeding before the court or involved in administrative proceedings before the tribunal.

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information is estimated for each respondent to average: 1 minute/employee, 4 minutes/Breath Alcohol Technician. Individuals may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to U.S. Department of Transportation, Drug Enforcement and Program Compliance, Room 9404, 400 Seventh St., SW, Washington, D.C. 20590 or Office of Management and Budget, Paperwork Reduction Project, Room 3001, 725 Seventeenth St., NW, Washington, D.C. 20503.

COPY 2 - EMPLOYEE RETAINS

OMB No. 2105-0529
Exp. Date: 2/28/97

U.S. Department of Transportation (DOT)
Breath Alcohol Testing Form

[THE INSTRUCTIONS FOR COMPLETING THIS FORM ARE ON THE BACK OF COPY 3]

▸ **STEP 1: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN**

A. Employee Name _____
(PRINT) (First, M.I., Last)

B. SSN or Employee ID No. _____

C. Employer Name, Address, & Telephone No. _____

_____

_____ ( ) _____
Telephone Number

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post-accident ☐ Return to Duty ☐ Follow-up

▸ **STEP 2: TO BE COMPLETED BY EMPLOYEE**

I certify that I am about to submit to breath alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on this form is true and correct.

_____ Date ___/___/___
Signature of Employee Month Day Year

▸ **STEP 3: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN**

I certify that I have conducted breath alcohol testing on the above named individual in accordance with the procedures established in the U.S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing devices identified, and that the results are as recorded.

Screening test: Complete only if the testing device is not designed to print the following.

Test No.	Testing Device Name	Testing Device Serial Number	Time AM PM	Result

Confirmation test: Confirmation test results MUST be affixed to the back of each copy of this form.

Remarks: _____

_____

_____

_____ _____ Date ___/___/___
(PRINT) Breath Alcohol Technician's Name (First, M.I., Last) Signature of Breath Alcohol Technician Month Day Year

▸ **STEP 4: TO BE COMPLETED BY EMPLOYEE**

I certify that I have submitted to the breath alcohol test the results of which are accurately recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment if the results are 0.02 or greater.

_____ Date ___/___/___
Signature of Employee Month Day Year

COPY 3 - BREATH ALCOHOL TECHNICIAN RETAINS

OMB No. 2105-0529
Exp. Date: 2/28/97

AFFIX SCREENING TEST RESULTS HERE (IF APPLICABLE)	AFFIX CONFIRMATION TEST RESULTS HERE
USE TAMPER-EVIDENT TAPE	USE TAMPER-EVIDENT TAPE

INSTRUCTIONS FOR COMPLETING THE U.S. DEPARTMENT OF TRANSPORTATION BREATH ALCOHOL TESTING FORM

NOTE: Use a ballpoint pen, press hard, and check all copies for legibility.

STEP 1 The Breath Alcohol Technician (BAT) completes the information required in this step. Be sure to print the employee's name and check the box identifying the reason for the test.

NOTE: If the employee refuses to provide SSN or I.D. number, be sure to indicate this in the remarks section in STEP 3. Proceed with STEP 2.

STEP 2 Instruct the employee to read, sign, and date the employee certification statement in STEP 2.

NOTE: If the employee refuses to sign the certification statement, do not proceed with the alcohol test. Contact the designated employer representative.

STEP 3 The Breath Alcohol Technician (BAT) completes the information required in this step. After conducting the alcohol screening test, do the following (as appropriate):

If the breath testing device used in conducting the screening test is not capable of printing the screening test information located on the front of this form (test number, testing device name, testing device serial number, time of test and results), complete this information in the space provided on the front of this form,

NOTE: Be sure to enter the result of the test exactly as it is indicated on the breath testing device, i.e., 0.00, 0.02, 0.04, etc.

OR, If the breath testing device used in conducting the screening test is capable of printing the screening test information located on the front of this form, affix the printed information in the space provided above. Be sure to use tamper-evident tape.

If the results of the screening test are less than 0.02, print, sign your name, and enter today's date in the space provided. Go to STEP 4.

If the results of the screening test are 0.02 or greater, a confirmation test must be administered in accordance with DOT regulations. An EVIDENTIAL BREATH TESTING device that is capable of printing confirmation test information must be used in conducting this test.

After conducting the alcohol confirmation test, affix the printed information in the space provided above. Be sure to use tamper-evident tape.

Print, sign your name, and enter the date in the space provided. Go to STEP 4.

STEP 4 Instruct the employee to read, sign, and date the employee certification statement in STEP 4.

NOTE: If the employee refuses to sign the certification statement in STEP 4, be sure to indicate this in the remarks section in STEP 3.

Forward Copy 1 (white page) to the employer.
Give Copy 2 (green page) to the employee.
Retain Copy 3 (blue page) for BAT records.

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information is estimated for each respondent to average: 1 minute/employee, 4 minutes/Breath Alcohol Technician. Individuals may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to U.S. Department of Transportation, Drug Enforcement and Program Compliance, Room 9404, 400 Seventh St., SW, Washington, D.C. 20590 or Office of Management and Budget, Paperwork Reduction Project, Room 3001, 725 Seventeenth St., NW, Washington, D.C. 20503.

COPY 3 - BREATH ALCOHOL TECHNICIAN RETAINS

OMB No. 2105-0529
Exp. Date: 2/28/97

[59 FR 43013, Aug. 19, 1994]