FEDERAL REGISTER

PART 40 - PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING

FERBRUARY 15, 1994

These procedures are current and apply unless they conflict with rules and regulations described in Attachment E.

Sec.

AUTHORITY: 49 U.S.C. 102, 301, 322.

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

§40.1 Applicability.

This part applies to transportation employers (including self-employed individuals) conducting drug urine testing programs pursuant to regulations issued by agencies of the Department of Transportation and to such transportation employers' officers, employees, agents and contractors, to the extent and in the manner provided in DOT agency regulations.

§40.3 Definitions.

For purposes of this part the following definitions apply:

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.

Chain of custody. Procedures to account for the integrity of each urine specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. 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 an initial examination of the urine specimen provided by those individuals.

Confirmatory test. A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial 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.)

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

DOT agency. An agency (or "operating administration") of the United States Department of Transportation administering regulations requiring compliance with this part, including the United States Coast Guard, the Federal Aviation Administration, the Federal Railroad Administration, the Federal Highway Administration, the Urban Mass Transportation Administration and the Research and Special Programs Administration.

Employee. An individual designated in a DOT agency regulation as subject to drug urine testing and the donor of a specimen under this part. 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, but no single employing entity is relieved of its responsibility for compliance with this part by virtue of participation in such a consortium or joint enterprise.

Initial test (also known as screening test). An immunoassay screen to elimi-

nate "negative" urine specimens from further consideration.

Medical Review Officer (MRO). A licensed physician 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.

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

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

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

§§ 40.5—40.19 [Reserved]

§ 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) Utilization of a standard drug testing custody and control form (carbonless manifold). The form shall be a multiple-part, carbonless record form with an original (copy 1), and a "second original" (copy 2), both of which shall accompany the specimen to the laboratory. Copies shall be provided for the Medical Review Officer (copy 3, to go directly to the MRO), the donor (copy 4), the collector (copy 5), and the employer representative (copy 6). If the employer desires to exercise the split sample option, then an additional copy of the urine custody and control form is required. This copy (copy 7) shall be the "split specimen original," and is to accompany the split specimen to the same lab, a second lab, or an employer storage site. There must be a positive link established between the first specimen and the split specimen through the specimen identification number; the split specimen identification number shall be an obvious derivative of the first specimen identification number. The form should be a permanent record on which identifying data on the donor, and on the specimen collection and transfer process, is retained. The form shall be constructed to display, at a minimum, the following elements, which shall appear on its respective parts as indicated:

(1) The following information shall appear on all parts of the form:

(i) A preprinted specimen identification number, which shall be unique to the particular collection. If the split sample option is exercised, the preprinted specimen identification number for split specimen shall be an obvious derivative of the first specimen; e.g., first specimen identification number suffixed "A," split specimen suffixed "B."

(ii) A block specifying the donor's employee identification number or Social Security number, which shall be entered by the collector.

(iii) A block specifying the employer's name, address, and identification number.

(iv) A block specifying the Medical Review Officer's name and address.

(v) Specification for which drugs the specimen identified by this form will be tested.

(vi) Specification for the reason for which this test conducted (preemployment, random, etc.), which shall be entered by the collector.

(vii) A block specifying whether or not the collector read the temperature within 4 minutes, and then notation, by the collector, that the temperature of specimen just read is within the range of 32.5–37.7C/90.5–99.8F; if not within the acceptable range, an area is provided to record the actual temperature.

(viii) A chain-of-custody block providing areas to enter the following information for each transfer of possession: Purpose of change; released by (signature/print name); received by (signature/print name); date. The words "Provide specimen for testing" and "DONOR" shall be preprinted in the initial spaces.

(ix) Information to be completed by the collector: Collector's name; date of collection; location of the collection site; a space for remarks at which unusual circumstances may be described; notation as to whether or not the split specimen was taken in accordance with Federal requirements *if* the option to offer the split specimen was exercised by the employer; and a certification statement as set forth below and a signature block with date which shall be completed by the collector:

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 3 of this form, that it bears the same identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(2) Information to be provided by the laboratory after analysis, which shall appear on parts 1, 2 and 7 (if applicable) of the form only: Accession number; laboratory name; address; a space for remarks; specimen results; and certification statement as set forth below, together with spaces to enter the printed name and signature of the certifying laboratory official and date:

I certify that the specimen identified by this accession number is the same specimen that bears the 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 below are for that specimen.

(3) A block to be completed by the Medical Review Officer (MRO), after the review of the specimen, which shall appear on parts 1, 2 and 7 (if applicable) of the form only, provides for the MRO's name, address, and certification, to read as follows, together with spaces for signature and date:

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

(4) Information to be provided by the donor, which shall appear on parts 3 through 6 of the form only: Donor name (printed); daytime phone number; date of birth; and certification statement as set forth below, together with a signature block with date which shall be completed by the donor.

I certify that I provided my urine specimen to the collector; that the specimen bottle was sealed with a tamper-proof seal in my presence; and that the information provided on this form and on the label affixed to the specimen bottle is correct.

(5) A statement to the donor which shall appear only on parts 3 and 4 of the form, as follows:

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 4—Donor) of this form—DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE YOUR COPY WITH YOU.

A form meeting the requirements of this paragraph is displayed at appendix A to this part.

(6) 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) may not be provided to the laboratory. Donor medical information may appear only on the copy provided to the donor.

(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 re-

mains in the restroom, or if the collection site person is expected to listen for use of unsecured sources of water.)

§ 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. 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 indi-

vidual 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 (32.5°–37.7 °C/90.5°–99.8 °F), and

(A) The employee declines to provide a measurement of oral body temperature, as provided in paragraph (f)(14) of the part; or

(B) Oral 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)(i) Upon receiving the specimen from the individual, the collection site person shall determine if it contains at least 60 milliliters of urine. If the individual is unable to provide a 60 milliliters of urine, the collection site person shall direct the individual to drink fluids and, after a reasonable time, again attempt to provide a complete sample using a fresh specimen bottle (and fresh collection container, if employed). The original specimen shall be discarded. If the employee is still unable to provide a complete specimen, the following rules apply:

(A) In the case of a post-accident test or test for reasonable cause (as defined by the DOT agency), the employee shall remain at the collection site and continue to consume reasonable quantities of fluids until the specimen has been provided or until the expiration of a period up to 8 hours from the beginning of the collection procedure.

(B) In the case of a preemployment test, random test, periodic test or other test not for cause (as defined by the DOT agency), the employer may elect to proceed as specified in paragraph (f)(10)(i)(A) of this section (consistent with any applicable restrictions on hours of service) or may elect to discontinue the collection and conduct a subsequent collection at a later time.

(C) If the employee cannot provide a complete sample within the up to 8-hour period or at the subsequent collection, as applicable, then the employer's MRO shall refer the individual for a medical evaluation to develop pertinent information concerning whether the individual's inability to provide a specimen is genuine or constitutes a refusal to provide a specimen. (In preemployment testing, if the employer does not wish to hire the individual, the MRO is not required to make such a referral.) Upon completion of the examination, the MRO shall report his or her conclusions to the employer in writing.

(ii) The employer may, but is not required to, use a "split sample" method of collection.

(A) The donor shall urinate into a collection container, which the collection site person, in the presence of the donor, after determining specimen temperature, pours into two specimen bottles.

(B) The first bottle is to be used for the DOT-mandated test, and 60 ml of urine shall be poured into it. If there is no additional urine available for the second specimen bottle, the first specimen bottle shall nevertheless be processed for testing.

(C) Up to 60 ml of the remainder of the urine shall be poured into the second specimen bottle.

(D) All requirements of this part shall be followed with respect to both samples, including the requirement that a copy of the chain of custody form accompany each bottle processed under "split sample" procedures.

341-193 O—93——18

(E) Any specimen collected under "split sample" procedures must be stored in a secured, refrigerated environment and an appropriate entry made in the chain of custody form.

(F) If the test of the first bottle is positive, the employee may request that the MRO direct that the second bottle be tested in a DHHS-certified laboratory for presence of the drug(s) for which a positive result was obtained in the test of the first bottle. The result of this test is transmitted to the MRO without regard to the cutoff values of §40.29. The MRO shall honor such a request if it is made within 72 hours of the employee's having actual notice that he or she tested positive.

(G) Action required by DOT 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 second test.

(H) If the result of the second test is negative, the MRO shall cancel the test.

(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 32.5°–37.7 °C/90.5°–99.8 °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. On the tape sealing the container, the collection site person shall sign and enter the date specimens were sealed in the shipping containers for shipment. The collection site person shall ensure that the chain of custody documentation is attached or enclosed in each container sealed for shipment to the drug testing laboratory.

(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 forms.* 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 shall be identified. Every effort shall be made

to minimize the number of persons handling specimens.

§ 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) 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.

(2) Specimen bottles generally shall be retained within the laboratory's accession area until all analyses have been completed. Aliquots and the laboratory's chain of custody forms shall be used by laboratory personnel for conducting initial and confirmatory tests.

(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	100
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	500

[1] Delta-9-tetrahydrocannabinol-9-carboxylic acid.
[2] Benzoylecgonine.

(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 decisionmaker 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 to the employer official responsible for coordination of the drug testing program a monthly statistical summary of urinalysis testing of the employer's employees and shall not include in the summary any personal identifying information. Initial and confirmation data shall be included from test results reported within that month. Normally this summary shall be forwarded by registered or certified mail not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

(i) Initial Testing:
(A) Number of specimens received;
(B) Number of specimens reported out; and
(C) Number of specimens screened positive for:

Marijuana metabolites
Cocaine metabolites
Opiate metabolites
Phencyclidine
Amphetamine

(ii) Confirmatory Testing:
(A) Number of specimens received for confirmation;
(B) Number of specimens confirmed positive for:

Marijuana metabolite
Cocaine metabolite
Morphine, codeine
Phencyclidine
Amphetamine
Methamphetamine

Monthly reports shall not include data from which it is reasonably likely that information about individuals' tests can be readily inferred. If necessary, in order to prevent the disclosure of such data, the laboratory shall not send a report until data are sufficiently aggregated to make such an inference unlikely. In any month in which a report is withheld for this reason, the laboratory will so inform the 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.

§ 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 lim-

ited 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) The MRO shall not be an employee of the laboratory conducting the drug test unless the laboratory establishes a clear separation of functions to prevent any appearance of a conflict of interest, including assuring that the MRO has no responsibility for, and is not supervised by or the supervisor of, any persons who have responsibility for the drug testing or quality control operations of the laboratory.

(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 expresaly declines the opportunity to discuss the test;

(ii) 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 (4) of this section), and more than five days have passed since the date the employee was successfully contacted by the designated employer representative; or

(iii) Other circumstances provided for in DOT agency drug testing regulations.

(6) If a test is verified positive under the circumstances specified in paragraph (c)(5)(ii) of this section, the employee may present to the MRO information documenting that serious illness, injury, or other circumstances unavoidably prevented the employee from timely contacting the MRO. 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) *Reanalysis authorized.* Should any question arise as to the accuracy or validity of a positive test result, only the Medical Review Officer is authorized to order a reanalysis of the original sample and such retests are authorized only at laboratories certified by DHHS. The Medical Review Officer shall authorize a reanalysis of the original sample if requested to do so by the employee within 72 hours of the employee's having received actual notice of the positive test. If the retest is negative, the MRO shall cancel the test.

(f) *Result consistent with legal drug use.* If the MRO determines there is a legitimate medical explanation for the positive test result, the MRO shall re-

port the test result to the employer as negative.

(g) *Result scientifically insufficient.* Additionally, the MRO, based on review of inspection reports, quality control data, multiple samples, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation the MRO may request reanalysis of the original sample before making this decision. (The MRO may request that reanalysis as provided in § 40.33(e) be performed by the same laboratory or, that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with the DHHS Guidelines.) The laboratory shall assist in this review process as requested by the MRO by making available the individual responsible for day-to-day management of the urine drug testing laboratory or other employee who is a forensic toxicologist or who has equivalent forensic experience in urine drug testing, to provide specific consultation as required by the employer. The employer shall include in any required annual report to a DOT agency a summary of any negative findings based on scientific insufficiency but shall not include any personal identifying information in such reports.

(h) *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.

§ 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 DHHS—certified laboratories.

Employers subject to this part shall use only laboratories certified under the DHHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs," 53 FR 11970, April 11, 1988, and subsequent amendments thereto.