

sent by July 31 of each year for January 1 through June 30 of the current year.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35971, June 25, 2008]

§ 40.113 Where is other information concerning laboratories found in this regulation?

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

- § 40.3—Definition.
- § 40.13—Prohibition on making specimens available for other purposes.
- § 40.31—Conflicts of interest concerning collectors.
- § 40.47—Laboratory rejections of test for improper form.
- § 40.125—Conflicts of interest concerning MROs.
- § 40.175—Role of first laboratory in split specimen tests.
- § 40.177—Role of second laboratory in split specimen tests (drugs).
- § 40.179—Role of second laboratory in split specimen tests (adulterants).
- § 40.181—Role of second laboratory in split specimen tests (substitution).
- §§ 40.183–40.185—Transmission of split specimen test results to MRO.
- §§ 40.201–40.205—Role in correcting errors.
- § 40.329—Release of information to employees.
- § 40.331—Limits on release of information.
- § 40.355—Role with respect to other service agents.

Subpart G—Medical Review Officers and the Verification Process

§ 40.121 Who is qualified to act as an MRO?

To be qualified to act as an MRO in the DOT drug testing program, you must meet each of the requirements of this section:

(a) *Credentials.* You must be a licensed physician (Doctor of Medicine or Osteopathy). If you are a licensed physician in any U.S., Canadian, or Mexican jurisdiction and meet the other requirements of this section, you are authorized to perform MRO services with respect to all covered employees, wherever they are located. For example, if you are licensed as an M.D. in one state or province in the U.S., Canada, or Mexico, you are not limited to performing MRO functions in that

state or province, and you may perform MRO functions for employees in other states or provinces without becoming licensed to practice medicine in the other jurisdictions.

(b) *Basic knowledge.* You must be knowledgeable in the following areas:

(1) You must be knowledgeable about and have clinical experience in controlled substances abuse disorders, including detailed knowledge of alternative medical explanations for laboratory confirmed drug test results.

(2) You must be knowledgeable about issues relating to adulterated and substituted specimens as well as the possible medical causes of specimens having an invalid result.

(3) You must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom you evaluate drug test results, and you must keep current on any changes to these materials. The DOT MRO Guidelines document is available from ODAPC (Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590, 202-366-3784, or on the ODAPC web site (<http://www.dot.gov/ost/dapc>)).

(c) *Qualification training.* You must receive qualification training meeting the requirements of this paragraph (c).

(1) Qualification training must provide instruction on the following subjects:

(i) Collection procedures for urine specimens;

(ii) Chain of custody, reporting, and recordkeeping;

(iii) Interpretation of drug and validity tests results;

(iv) The role and responsibilities of the MRO in the DOT drug testing program;

(v) The interaction with other participants in the program (*e.g.*, DERs, SAPs); and

(vi) Provisions of this part and DOT agency rules applying to employers for whom you review test results, including changes and updates to this part and DOT agency rules, guidance, interpretations, and policies affecting the performance of MRO functions, as well as issues that MROs confront in carrying out their duties under this part and DOT agency rules.

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(2) Following your completion of qualification training under paragraph (c)(1) of this section, you must satisfactorily complete an examination administered by a nationally-recognized MRO certification board or subspecialty board for medical practitioners in the field of medical review of DOT-mandated drug tests. The examination must comprehensively cover all the elements of qualification training listed in paragraph (c)(1) of this section.

(3) The following is the schedule for qualification training you must meet:

(i) If you became an MRO before August 1, 2001, and have already met the qualification training requirement, you do not have to meet it again.

(ii) If you became an MRO before August 1, 2001, but have not yet met the qualification training requirement, you must do so no later than January 31, 2003.

(iii) If you become an MRO on or after August 1, 2001, you must meet the qualification training requirement before you begin to perform MRO functions.

(d) *Continuing Education.* During each three-year period from the date on which you satisfactorily complete the examination under paragraph (c)(2) of this section, you must complete continuing education consisting of at least 12 professional development hours (*e.g.*, Continuing Education Medical Units) relevant to performing MRO functions.

(1) This continuing education must include material concerning new technologies, interpretations, recent guidance, rule changes, and other information about developments in MRO practice, pertaining to the DOT program, since the time you met the qualification training requirements of this section.

(2) Your continuing education activities must include assessment tools to assist you in determining whether you have adequately learned the material.

(3) If you are an MRO who completed the qualification training and examination requirements prior to August 1, 2001, you must complete your first increment of 12 CEU hours before August 1, 2004.

(e) *Documentation.* You must maintain documentation showing that you currently meet all requirements of this

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section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are using or negotiating to use your services.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

§ 40.123 What are the MRO's responsibilities in the DOT drug testing program?

As an MRO, you have the following basic responsibilities:

(a) Acting as an independent and impartial "gatekeeper" and advocate for the accuracy and integrity of the drug testing process.

(b) Providing a quality assurance review of the drug testing process for the specimens under your purview. This includes, but is not limited to:

(1) Ensuring the review of the CCF on all specimen collections for the purposes of determining whether there is a problem that may cause a test to be cancelled (see §§ 40.199-40.203). As an MRO, you are not required to review laboratory internal chain of custody documentation. No one is permitted to cancel a test because you have not reviewed this documentation;

(2) Providing feedback to employers, collection sites and laboratories regarding performance issues where necessary; and

(3) Reporting to and consulting with the ODAPC or a relevant DOT agency when you wish DOT assistance in resolving any program issue. As an employer or service agent, you are prohibited from limiting or attempting to limit the MRO's access to DOT for this purpose and from retaliating in any way against an MRO for discussing drug testing issues with DOT.

(c) You must determine whether there is a legitimate medical explanation for confirmed positive, adulterated, substituted, and invalid drug tests results from the laboratory.

(d) While you provide medical review of employees' test results, this part does not deem that you have established a doctor-patient relationship with the employees whose tests you review.

(e) You must act to investigate and correct problems where possible and notify appropriate parties (*e.g.*, HHS,

DOT, employers, service agents) where assistance is needed, (*e.g.*, cancelled or problematic tests, incorrect results, problems with blind specimens).

(f) You must ensure the timely flow of test results and other information to employers.

(g) You must protect the confidentiality of the drug testing information.

(h) You must perform all your functions in compliance with this part and other DOT agency regulations.

§ 40.125 What relationship may an MRO have with a laboratory?

As an MRO, you may not enter into any relationship with an employer's laboratory that creates a conflict of interest or the appearance of a conflict of interest with your responsibilities to that employer. You may not derive any financial benefit by having an employer use a specific laboratory. For examples of relationships between laboratories and MROs that the Department views as creating a conflict of interest or the appearance of such a conflict, see § 40.101(b).

§ 40.127 What are the MRO's functions in reviewing negative test results?

As the MRO, you must do the following with respect to negative drug test results you receive from a laboratory, prior to verifying the result and releasing it to the DER:

(a) Review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require you to initiate corrective action or to cancel the test (see §§ 40.199 and 40.203).

(b) Review the negative laboratory test result and ensure that it is consistent with the information contained on the CCF.

(c) Before you report a negative test result, you must have in your possession the following documents:

(1) Copy 2 of the CCF, a legible copy of it, or any other CCF copy containing the employee's signature; and

(2) A legible copy (fax, photocopy, image) of Copy 1 of the CCF or the electronic laboratory results report that conveys the negative laboratory test result.

(d) If the copy of the documentation provided to you by the collector or laboratory appears unclear, you must re-

quest that the collector or laboratory send you a legible copy.

(e) On Copy 2 of the CCF, place a check mark in the "Negative" box (Step 6), provide your name, and sign, initial, or stamp and date the verification statement.

(f) Report the result in a confidential manner (see §§ 40.163–40.167).

(g) Staff under your direct, personal supervision may perform the administrative functions of this section for you, but only you can cancel a test. If you cancel a laboratory-confirmed negative result, check the "Test Cancelled" box (Step 6) on Copy 2 of the CCF, make appropriate annotation in the "Remarks" line, provide your name, and sign, initial or stamp and date the verification statement.

(1) On specimen results that are reviewed by your staff, you are responsible for assuring the quality of their work.

(2) You are required to personally review at least 5 percent of all CCFs reviewed by your staff on a quarterly basis, including all results that required a corrective action. However, you need not review more than 500 negative results in any quarter.

(3) Your review must, as a minimum, include the CCF, negative laboratory test result, any accompanying corrective documents, and the report sent to the employer. You must correct any errors that you discover. You must take action as necessary to ensure compliance by your staff with this part and document your corrective action. You must attest to the quality assurance review by initialing the CCFs that you review.

(4) You must make these CCFs easily identifiable and retrievable by you for review by DOT agencies.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

§ 40.129 What are the MRO's functions in reviewing laboratory confirmed non-negative drug test results?

(a) As the MRO, you must do the following with respect to confirmed positive, adulterated, substituted, or invalid drug tests you receive from a laboratory, before you verify the result and release it to the DER:

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(1) Review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require you to cancel the test (see §§ 40.199 and 40.203). Staff under your direct, personal supervision may conduct this administrative review for you, but only you may verify or cancel a test.

(2) Review Copy 1 of the CCF and ensure that it is consistent with the information contained on Copy 2, that the test result is legible, and that the certifying scientist signed the form. You are not required to review any other documentation generated by the laboratory during their analysis or handling of the specimen (*e.g.*, the laboratory internal chain of custody).

(3) If the copy of the documentation provided to you by the collector or laboratory appears unclear, you must request that the collector or laboratory send you a legible copy.

(4) Except in the circumstances spelled out in § 40.133, conduct a verification interview. This interview must include direct contact in person or by telephone between you and the employee. You may initiate the verification process based on the laboratory results report.

(5) Verify the test result, consistent with the requirements of §§ 40.135 through 40.145, 40.159, and 40.160, as:

- (i) Negative; or
- (ii) Cancelled; or
- (iii) Positive, and/or refusal to test because of adulteration or substitution.

(b) Before you report a verified negative, positive, test cancelled, refusal to test because of adulteration or substitution, you must have in your possession the following documents:

(1) Copy 2 of the CCF, a legible copy of it, or any other CCF copy containing the employee's signature; and

(2) A legible copy (fax, photocopy, image) of Copy 1 of the CCF, containing the certifying scientist's signature.

(c) With respect to verified positive test results, place a check mark in the "Positive" box (Step 6) on Copy 2 of the CCF, indicate the drug(s)/ metabolite(s) detected on the "Remarks" line, sign and date the verification statement.

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(d) If you cancel a laboratory confirmed positive, adulterated, substituted, or invalid drug test report, check the "test cancelled" box (Step 6) on Copy 2 of the CCF, make appropriate annotation in the "Remarks" line, sign, provide your name, and date the verification statement.

(e) Report the result in a confidential manner (see §§ 40.163-40.167).

(f) With respect to adulteration or substitution test results, check the "refusal to test because:" box (Step 6) on Copy 2 of the CCF, check the "Adulterated" or "Substituted" box, as appropriate, make appropriate annotation in the "Remarks" line, sign and date the verification statement.

(g) As the MRO, your actions concerning reporting confirmed positive, adulterated, or substituted results to the employer before you have completed the verification process are also governed by the stand-down provisions of § 40.21.

(1) If an employer has a stand-down policy that meets the requirements of § 40.21, you may report to the DER that you have received an employee's laboratory confirmed positive, adulterated, or substituted test result, consistent with the terms of the waiver the employer received. You must not provide any further details about the test result (*e.g.*, the name of the drug involved).

(2) If the employer does not have a stand-down policy that meets the requirements of § 40.21, you must not inform the employer that you have received an employee's laboratory confirmed positive, adulterated, or substituted test result until you verify the test result. For example, as an MRO employed directly by a company, you must not tell anyone on the company's staff or management that you have received an employee's laboratory confirmed test result.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 73 FR 35971, June 25, 2008]

§ 40.131 How does the MRO or DER notify an employee of the verification process after receiving laboratory confirmed non-negative drug test results?

(a) When, as the MRO, you receive a confirmed positive, adulterated, substituted, or invalid test result from the laboratory, you must contact the employee directly (*i.e.*, actually talk to the employee), on a confidential basis, to determine whether the employee wants to discuss the test result. In making this contact, you must explain to the employee that, if he or she declines to discuss the result, you will verify the test as positive or as a refusal to test because of adulteration or substitution, as applicable.

(b) As the MRO, staff under your personal supervision may conduct this initial contact for you.

(1) This staff contact must be limited to scheduling the discussion between you and the employee and explaining the consequences of the employee's declining to speak with you (*i.e.*, that the MRO will verify the test without input from the employee). If the employee declines to speak with you, the staff person must document the employee's decision, including the date and time.

(2) A staff person must not gather any medical information or information concerning possible explanations for the test result.

(3) A staff person may advise an employee to have medical information (*e.g.*, prescriptions, information forming the basis of a legitimate medical explanation for a confirmed positive test result) ready to present at the interview with the MRO.

(4) Since you are required to speak personally with the employee, face-to-face or on the phone, your staff must not inquire if the employee wishes to speak with you.

(c) As the MRO, you or your staff must make reasonable efforts to reach the employee at the day and evening telephone numbers listed on the CCF. Reasonable efforts include, as a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the employee at the day and evening telephone numbers listed on the CCF. If you or your staff cannot reach the employee directly after making these ef-

forts, you or your staff must take the following steps:

(1) Document the efforts you made to contact the employee, including dates and times. If both phone numbers are incorrect (*e.g.*, disconnected, wrong number), you may take the actions listed in paragraph (c)(2) of this section without waiting the full 24-hour period.

(2) Contact the DER, instructing the DER to contact the employee.

(i) You must simply direct the DER to inform the employee to contact you.

(ii) You must not inform the DER that the employee has a confirmed positive, adulterated, substituted, or invalid test result.

(iii) You must document the dates and times of your attempts to contact the DER, and you must document the name of the DER you contacted and the date and time of the contact.

(d) As the DER, you must attempt to contact the employee immediately, using procedures that protect, as much as possible, the confidentiality of the MRO's request that the employee contact the MRO. If you successfully contact the employee (*i.e.*, actually talk to the employee), you must document the date and time of the contact, and inform the MRO. You must inform the employee that he or she should contact the MRO immediately. You must also inform the employee of the consequences of failing to contact the MRO within the next 72 hours (see § 40.133(a)(2)).

(1) As the DER, you must not inform anyone else working for the employer that you are seeking to contact the employee on behalf of the MRO.

(2) If, as the DER, you have made all reasonable efforts to contact the employee but failed to do so, you may place the employee on temporary medically unqualified status or medical leave. Reasonable efforts include, as a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the employee at the day and evening telephone numbers listed on the CCF.

(i) As the DER, you must document the dates and times of these efforts.

(ii) If, as the DER, you are unable to contact the employee within this 24-hour period, you must leave a message for the employee by any practicable means (*e.g.*, voice mail, e-mail, letter)

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to contact the MRO and inform the MRO of the date and time of this attempted contact.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 69 FR 64867, Nov. 9, 2004]

§ 40.133 Without interviewing the employee, under what circumstances may the MRO verify a test result as positive, or as a refusal to test because of adulteration or substitution, or as cancelled because the test was invalid?

(a) As the MRO, you normally may verify a confirmed positive test (for any drug or drug metabolite, including opiates), or as a refusal to test because of adulteration or substitution, only after interviewing the employee as provided in §§ 40.135–40.145. However, there are three circumstances in which you may verify such a result without an interview:

(1) You may verify a test result as a positive or refusal to test, as applicable, if the employee expressly declines the opportunity to discuss the test with you. You must maintain complete documentation of this occurrence, including notation of informing, or attempting to inform, the employee of the consequences of not exercising the option to speak with the you.

(2) You may verify a test result as a positive or refusal to test, as applicable, if the DER has successfully made and documented a contact with the employee and instructed the employee to contact you and more than 72 hours have passed since the time the DER contacted the employee.

(3) You may verify a test result as a positive or refusal to test, as applicable, if neither you nor the DER, after making and documenting all reasonable efforts, has been able to contact the employee within ten days of the date on which the MRO receives the confirmed test result from the laboratory.

(b) As the MRO, you may verify an invalid test result as cancelled (with instructions to recollect immediately under direct observation) without interviewing the employee, as provided at § 40.159:

(1) If the employee expressly declines the opportunity to discuss the test with you;

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(2) If the DER has successfully made and documented a contact with the employee and instructed the employee to contact you and more than 72 hours have passed since the time the DER contacted the employee; or

(3) If neither you nor the DER, after making and documenting all reasonable efforts, has been able to contact the employee within ten days of the date on which you received the confirmed invalid test result from the laboratory.

(c) As the MRO, after you verify a test result as a positive or as a refusal to test under this section, you must document the date and time and reason, following the instructions in § 40.163. For a cancelled test due to an invalid result under this section, you must follow the instructions in § 40.159(a)(5).

(d) As the MRO, after you have verified a test result under this section and reported the result to the DER, you must allow the employee to present information to you within 60 days of the verification to document that serious illness, injury, or other circumstances unavoidably precluded contact with the MRO and/or DER in the times provided. On the basis of such information, you may reopen the verification, allowing the employee to present information concerning whether there is a legitimate medical explanation of the confirmed test result.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35971, June 25, 2008]

§ 40.135 What does the MRO tell the employee at the beginning of the verification interview?

(a) As the MRO, you must tell the employee that the laboratory has determined that the employee's test result was positive, adulterated, substituted, or invalid, as applicable. You must also tell the employee of the drugs for which his or her specimen tested positive, or the basis for the finding of adulteration or substitution.

(b) You must explain the verification interview process to the employee and inform the employee that your decision will be based on information the employee provides in the interview.

(c) You must explain that, if further medical evaluation is needed for the

verification process, the employee must comply with your request for this evaluation and that failure to do so is equivalent of expressly declining to discuss the test result.

(d) As the MRO, you must warn an employee who has a confirmed positive, adulterated, substituted or invalid test that you are required to provide to third parties drug test result information and medical information affecting the performance of safety-sensitive duties that the employee gives you in the verification process without the employee's consent (see § 40.327).

(1) You must give this warning to the employee before obtaining any medical information as part of the verification process.

(2) For purposes of this paragraph (d), medical information includes information on medications or other substances affecting the performance of safety-sensitive duties that the employee reports using or medical conditions the employee reports having.

(3) For purposes of this paragraph (d), the persons to whom this information may be provided include the employer, a SAP evaluating the employee as part of the return to duty process (see § 40.293(g)), DOT, another Federal safety agency (e.g., the NTSB), or any state safety agency as required by state law.

(e) You must also advise the employee that, after informing any third party about any medication the employee is using pursuant to a legally valid prescription under the Controlled Substances Act, you will allow 5 days for the employee to have the prescribing physician contact you to determine if the medication can be changed to one that does not make the employee medically unqualified or does not pose a significant safety risk. If, as an MRO, you receive such information from the prescribing physician, you must transmit this information to any third party to whom you previously provided information about the safety risks of the employee's other medication.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001]

§ 40.137 On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, or PCP?

(a) As the MRO, you must verify a confirmed positive test result for marijuana, cocaine, amphetamines, and/or PCP unless the employee presents a legitimate medical explanation for the presence of the drug(s)/metabolite(s) in his or her system.

(b) You must offer the employee an opportunity to present a legitimate medical explanation in all cases.

(c) The employee has the burden of proof that a legitimate medical explanation exists. The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the employee for this purpose for up to five days before verifying the test result, if you determine that there is a reasonable basis to believe that the employee will be able to produce relevant evidence concerning a legitimate medical explanation within that time.

(d) If you determine that there is a legitimate medical explanation, you must verify the test result as negative. Otherwise, you must verify the test result as positive.

(e) In determining whether a legitimate medical explanation exists, you may consider the employee's use of a medication from a foreign country. You must exercise your professional judgment consistently with the following principles:

(1) There can be a legitimate medical explanation only with respect to a substance that is obtained legally in a foreign country.

(2) There can be a legitimate medical explanation only with respect to a substance that has a legitimate medical use. Use of a drug of abuse (e.g., heroin, PCP, marijuana) or any other substance (see § 40.151(f) and (g)) that cannot be viewed as having a legitimate medical use can never be the basis for a legitimate medical explanation, even if the substance is obtained legally in a foreign country.

(3) Use of the substance can form the basis of a legitimate medical explanation only if it is used consistently

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with its proper and intended medical purpose.

(4) Even if you find that there is a legitimate medical explanation under this paragraph (e) and verify a test negative, you may have a responsibility to raise fitness-for-duty considerations with the employer (see § 40.327).

§ 40.139 On what basis does the MRO verify test results involving opiates?

As the MRO, you must proceed as follows when you receive a laboratory confirmed positive opiate result:

(a) If the laboratory detects the presence of 6-acetylmorphine (6-AM) in the specimen, you must verify the test result positive.

(b) In the absence of 6-AM, if the laboratory detects the presence of either morphine or codeine at 15,000 ng/mL or above, you must verify the test result positive unless the employee presents a legitimate medical explanation for the presence of the drug or drug metabolite in his or her system, as in the case of other drugs (see § 40.137). Consumption of food products (*e.g.*, poppy seeds) must not be considered a legitimate medical explanation for the employee having morphine or codeine at these concentrations.

(c) For all other opiate positive results, you must verify a confirmed positive test result for opiates only if you determine that there is clinical evidence, in addition to the urine test, of unauthorized use of any opium, opiate, or opium derivative (*i.e.*, morphine, heroin, or codeine).

(1) As an MRO, it is your responsibility to use your best professional and ethical judgement and discretion to determine whether there is clinical evidence of unauthorized use of opiates. Examples of information that you may consider in making this judgement include, but are not limited to, the following:

- (i) Recent needle tracks;
- (ii) Behavioral and psychological signs of acute opiate intoxication or withdrawal;
- (iii) Clinical history of unauthorized use recent enough to have produced the laboratory test result;

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(iv) Use of a medication from a foreign country. See § 40.137(e) for guidance on how to make this determination.

(2) In order to establish the clinical evidence referenced in paragraphs (c)(1)(i) and (ii) of this section, personal observation of the employee is essential.

(i) Therefore, you, as the MRO, must conduct, or cause another physician to conduct, a face-to-face examination of the employee.

(ii) No face-to-face examination is needed in establishing the clinical evidence referenced in paragraph (c)(1)(iii) or (iv) of this section.

(3) To be the basis of a verified positive result for opiates, the clinical evidence you find must concern a drug that the laboratory found in the specimen. (For example, if the test confirmed the presence of codeine, and the employee admits to unauthorized use of hydrocodone, you do not have grounds for verifying the test positive. The admission must be for the substance that was found).

(4) As the MRO, you have the burden of establishing that there is clinical evidence of unauthorized use of opiates referenced in this paragraph (c). If you cannot make this determination (*e.g.*, there is not sufficient clinical evidence or history), you must verify the test as negative. The employee does not need to show you that a legitimate medical explanation exists if no clinical evidence is established.

§ 40.141 How does the MRO obtain information for the verification decision?

As the MRO, you must do the following as you make the determinations needed for a verification decision:

(a) You must conduct a medical interview. You must review the employee's medical history and any other relevant biomedical factors presented to you by the employee. You may direct the employee to undergo further medical evaluation by you or another physician.

(b) If the employee asserts that the presence of a drug or drug metabolite in his or her specimen results from taking prescription medication, you must review and take all reasonable

and necessary steps to verify the authenticity of all medical records the employee provides. You may contact the employee's physician or other relevant medical personnel for further information.

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§ 40.145 On what basis does the MRO verify test results involving adulteration or substitution?

(a) As an MRO, when you receive a laboratory report that a specimen is adulterated or substituted, you must treat that report in the same way you treat the laboratory's report of a confirmed positive for a drug or drug metabolite.

(b) You must follow the same procedures used for verification of a confirmed positive test for a drug or drug metabolite (see §§ 40.129–40.135, 40.141, 40.151), except as otherwise provided in this section.

(c) In the verification interview, you must explain the laboratory findings to the employee and address technical questions or issues the employee may raise.

(d) You must offer the employee the opportunity to present a legitimate medical explanation for the laboratory findings with respect to presence of the adulterant in, or the creatinine and specific gravity findings for, the specimen.

(e) The employee has the burden of proof that there is a legitimate medical explanation.

(1) To meet this burden in the case of an adulterated specimen, the employee must demonstrate that the adulterant found by the laboratory entered the specimen through physiological means.

(2) To meet this burden in the case of a substituted specimen, the employee must demonstrate that he or she did produce or could have produced urine through physiological means, meeting the creatinine concentration criterion of less than 2 mg/dL and the specific gravity criteria of less than or equal to 1.0010 or greater than or equal to 1.0200 (see § 40.93(b)).

(3) The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the em-

ployee for this purpose for up to five days before verifying the specimen, if you determine that there is a reasonable basis to believe that the employee will be able to produce relevant evidence supporting a legitimate medical explanation within that time.

(f) As the MRO or the employer, you are not responsible for arranging, conducting, or paying for any studies, examinations or analyses to determine whether a legitimate medical explanation exists.

(g) As the MRO, you must exercise your best professional judgment in deciding whether the employee has established a legitimate medical explanation.

(1) If you determine that the employee's explanation does not present a reasonable basis for concluding that there may be a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution, as applicable.

(2) If you believe that the employee's explanation may present a reasonable basis for concluding that there is a legitimate medical explanation, you must direct the employee to obtain, within the five-day period set forth in paragraph (e)(3) of this section, a further medical evaluation. This evaluation must be performed by a licensed physician (the "referral physician"), acceptable to you, with expertise in the medical issues raised by the employee's explanation. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(i) As the MRO or employer, you are not responsible for finding or paying a referral physician. However, on request of the employee, you must provide reasonable assistance to the employee's efforts to find such a physician. The final choice of the referral physician is the employee's, as long as the physician is acceptable to you.

(ii) As the MRO, you must consult with the referral physician, providing guidance to him or her concerning his or her responsibilities under this section. As part of this consultation, you must provide the following information to the referral physician:

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(A) That the employee was required to take a DOT drug test, but the laboratory reported that the specimen was adulterated or substituted, which is treated as a refusal to test;

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

(C) That the referral physician must agree to follow the requirements of paragraphs (g)(3) through (g)(4) of this section; and

(D) That the referral physician must provide you with a signed statement of his or her recommendations.

(3) As the referral physician, you must evaluate the employee and consider any evidence the employee presents concerning the employee's medical explanation. You may conduct additional tests to determine whether there is a legitimate medical explanation. Any additional urine tests must be performed in an HHS-certified laboratory.

(4) As the referral physician, you must then make a written recommendation to the MRO about whether the MRO should determine that there is a legitimate medical explanation. As the MRO, you must seriously consider and assess the referral physician's recommendation in deciding whether there is a legitimate medical explanation.

(5) As the MRO, if you determine that there is a legitimate medical explanation, you must cancel the test and inform ODAPC in writing of the determination and the basis for it (*e.g.*, referral physician's findings, evidence produced by the employee).

(6) As the MRO, if you determine that there is not a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution.

(h) The following are examples of types of evidence an employee could present to support an assertion of a legitimate medical explanation for a substituted result.

(1) Medically valid evidence demonstrating that the employee is capable of physiologically producing urine meeting the creatinine and specific gravity criteria of § 40.93(b).

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(i) To be regarded as medically valid, the evidence must have been gathered using appropriate methodology and controls to ensure its accuracy and reliability.

(ii) Assertion by the employee that his or her personal characteristics (*e.g.*, with respect to race, gender, weight, diet, working conditions) are responsible for the substituted result does not, in itself, constitute a legitimate medical explanation. To make a case that there is a legitimate medical explanation, the employee must present evidence showing that the cited personal characteristics actually result in the physiological production of urine meeting the creatinine and specific gravity criteria of § 40.93(b).

(2) Information from a medical evaluation under paragraph (g) of this section that the individual has a medical condition that has been demonstrated to cause the employee to physiologically produce urine meeting the creatinine and specific gravity criteria of § 40.93(b).

(i) A finding or diagnosis by the physician that an employee has a medical condition, in itself, does not constitute a legitimate medical explanation.

(ii) To establish there is a legitimate medical explanation, the employee must demonstrate that the cited medical condition actually results in the physiological production of urine meeting the creatinine and specific gravity criteria of § 40.93(b).

[65 FR 79526, Dec. 19, 2000, as amended at 68 FR 31626, May 28, 2003; 69 FR 64867, Nov. 9, 2004]

§ 40.147 [Reserved]

§ 40.149 May the MRO change a verified drug test result?

(a) As the MRO, you may change a verified test result only in the following situations:

(1) When you have reopened a verification that was done without an interview with an employee (see § 40.133(d)).

(2) If you receive information, not available to you at the time of the original verification, demonstrating that the laboratory made an error in identifying (*e.g.*, a paperwork mistake)

or testing (*e.g.*, a false positive or negative) the employee's primary or split specimen. For example, suppose the laboratory originally reported a positive test result for Employee X and a negative result for Employee Y. You verified the test results as reported to you. Then the laboratory notifies you that it mixed up the two test results, and X was really negative and Y was really positive. You would change X's test result from positive to negative and contact Y to conduct a verification interview.

(3) If, within 60 days of the original verification decision—

(i) You receive information that could not reasonably have been provided to you at the time of the decision demonstrating that there is a legitimate medical explanation for the presence of drug(s)/metabolite(s) in the employee's specimen; or

(ii) You receive credible new or additional evidence that a legitimate medical explanation for an adulterated or substituted result exists.

Example to Paragraph (a)(3): If the employee's physician provides you a valid prescription that he or she failed to find at the time of the original verification, you may change the test result from positive to negative if you conclude that the prescription provides a legitimate medical explanation for the drug(s)/metabolite(s) in the employee's specimen.

(4) If you receive the information in paragraph (a)(3) of this section after the 60-day period, you must consult with ODAPC prior to changing the result.

(5) When you have made an administrative error and reported an incorrect result.

(b) If you change the result, you must immediately notify the DER in writing, as provided in §§ 40.163–40.165.

(c) You are the only person permitted to change a verified test result, such as a verified positive test result or a determination that an individual has refused to test because of adulteration or substitution. This is because, as the MRO, you have the sole authority under this part to make medical determinations leading to a verified test (*e.g.*, a determination that there was or was not a legitimate medical explanation for a laboratory test result).

For example, an arbitrator is not permitted to overturn the medical judgment of the MRO that the employee failed to present a legitimate medical explanation for a positive, adulterated, or substituted test result of his or her specimen.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 73 FR 35971, June 25, 2008]

§ 40.151 What are MROs prohibited from doing as part of the verification process?

As an MRO, you are prohibited from doing the following as part of the verification process:

(a) You must not consider any evidence from tests of urine samples or other body fluids or tissues (*e.g.*, blood or hair samples) that are not collected or tested in accordance with this part. For example, if an employee tells you he went to his own physician, provided a urine specimen, sent it to a laboratory, and received a negative test result or a DNA test result questioning the identity of his DOT specimen, you are required to ignore this test result.

(b) It is not your function to make decisions about factual disputes between the employee and the collector concerning matters occurring at the collection site that are not reflected on the CCF (*e.g.*, concerning allegations that the collector left the area or left open urine containers where other people could access them).

(c) It is not your function to determine whether the employer should have directed that a test occur. For example, if an employee tells you that the employer misidentified her as the subject of a random test, or directed her to take a reasonable suspicion or post-accident test without proper grounds under a DOT agency drug or alcohol regulation, you must inform the employee that you cannot play a role in deciding these issues.

(d) It is not your function to consider explanations of confirmed positive, adulterated, or substituted test results that would not, even if true, constitute a legitimate medical explanation. For example, an employee may tell you that someone slipped amphetamines into her drink at a party, that she unknowingly ingested a marijuana

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brownie, or that she traveled in a closed car with several people smoking crack. MROs are unlikely to be able to verify the facts of such passive or unknowing ingestion stories. Even if true, such stories do not present a legitimate medical explanation. Consequently, you must not declare a test as negative based on an explanation of this kind.

(e) You must not verify a test negative based on information that a physician recommended that the employee use a drug listed in Schedule I of the Controlled Substances Act. (*e.g.*, under a state law that purports to authorize such recommendations, such as the “medical marijuana” laws that some states have adopted).

(f) You must not accept an assertion of consumption or other use of a hemp or other non-prescription marijuana-related product as a basis for verifying a marijuana test negative. You also must not accept such an explanation related to consumption of coca teas as a basis for verifying a cocaine test result as negative. Consuming or using such a product is not a legitimate medical explanation.

(g) You must not accept an assertion that there is a legitimate medical explanation for the presence of PCP or 6-AM in a specimen. There are no legitimate medical explanations for the presence of these substances.

(h) You must not accept, as a legitimate medical explanation for an adulterated specimen, an assertion that soap, bleach, or glutaraldehyde entered a specimen through physiological means. There are no physiological means through which these substances can enter a specimen.

(i) You must not accept, as a legitimate medical explanation for a substituted specimen, an assertion that an employee can produce urine with no detectable creatinine. There are no physiological means through which a person can produce a urine specimen having this characteristic.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001]

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§ 40.153 How does the MRO notify employees of their right to a test of the split specimen?

(a) As the MRO, when you have verified a drug test as positive for a drug or drug metabolite, or as a refusal to test because of adulteration or substitution, you must notify the employee of his or her right to have the split specimen tested. You must also notify the employee of the procedures for requesting a test of the split specimen.

(b) You must inform the employee that he or she has 72 hours from the time you provide this notification to him or her to request a test of the split specimen.

(c) You must tell the employee how to contact you to make this request. You must provide telephone numbers or other information that will allow the employee to make this request. As the MRO, you must have the ability to receive the employee’s calls at all times during the 72 hour period (*e.g.*, by use of an answering machine with a “time stamp” feature when there is no one in your office to answer the phone).

(d) You must tell the employee that if he or she makes this request within 72 hours, the employer must ensure that the test takes place, and that the employee is not required to pay for the test from his or her own funds before the test takes place. You must also tell the employee that the employer may seek reimbursement for the cost of the test (see § 40.173).

(e) You must tell the employee that additional tests of the specimen (*e.g.*, DNA tests) are not authorized.

§ 40.155 What does the MRO do when a negative or positive test result is also dilute?

(a) When the laboratory reports that a specimen is dilute, you must, as the MRO, report to the DER that the specimen, in addition to being negative or positive, is dilute.

(b) You must check the “dilute” box (Step 6) on Copy 2 of the CCF.

(c) When you report a dilute specimen to the DER, you must explain to the DER the employer’s obligations and choices under § 40.197, to include the requirement for an immediate recollection under direct observation if

the creatinine concentration of a negative-dilute specimen was greater than or equal to 2mg/dL but less than or equal to 5mg/dL.

(d) If the employee's recollection under direct observation, in paragraph (c) of this section, results in another negative-dilute, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF documentation shows that the recollection was directly observed as required, report this result to the DER as a negative-dilute result.

(3) If CCF documentation indicates that the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 69 FR 64867, Nov. 9, 2004; 73 FR 35971, June 25, 2008]

§ 40.157 [Reserved]

§ 40.159 What does the MRO do when a drug test result is invalid?

(a) As the MRO, when the laboratory reports that the test result is an invalid result, you must do the following:

(1) Discuss the laboratory results with a certifying scientist to determine if the primary specimen should be tested at another HHS certified laboratory. If the laboratory did not contact you as required by §§ 40.91(e) and 40.96(c), you must contact the laboratory.

(2) If you and the laboratory have determined that no further testing is necessary, contact the employee and inform the employee that the specimen was invalid. In contacting the employee, use the procedures set forth in § 40.131.

(3) After explaining the limits of disclosure (see §§ 40.135(d) and 40.327), you must determine if the employee has a medical explanation for the invalid result. You must inquire about the medications the employee may have taken.

(4) If the employee gives an explanation that is acceptable, you must:

(i) Place a check mark in the "Test Cancelled" box (Step 6) on Copy 2 of the CCF and enter "Invalid Result"

and "direct observation collection not required" on the "Remarks" line.

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that no further action is required unless a negative test result is required (*i.e.*, pre-employment, return-to-duty, or follow-up tests).

(iii) If a negative test result is required and the medical explanation concerns a situation in which the employee has a permanent or long-term medical condition that precludes him or her from providing a valid specimen, as the MRO, you must follow the procedures outlined at § 40.160 for determining if there is clinical evidence that the individual is an illicit drug user.

(5) If the employee is unable to provide an explanation and/or a valid prescription for a medication that interfered with the immunoassay test but denies having adulterated the specimen, you must:

(i) Place a check mark in the "Test Cancelled" box (Step 6) on Copy 2 of the CCF and enter "Invalid Result" and "direct observation collection required" on the "Remarks" line.

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that a second collection must take place immediately under direct observation.

(iii) Instruct the employer to ensure that the employee has the minimum possible advance notice that he or she must go to the collection site.

(b) You may only report an invalid test result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

(c) If the employee admits to having adulterated or substituted the specimen, you must, on the same day, write and sign your own statement of what the employee told you. You must then report a refusal to test in accordance with § 40.163.

(d) If the employee admits to using a drug, you must, on the same day, write and sign your own statement of what the employee told you. You must then report that admission to the DER for appropriate action under DOT Agency

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regulations. This test will be reported as cancelled with the reason noted.

(e) If the employee's recollection (required at paragraph (a)(5) of this section) results in another invalid result for the same reason as reported for the first specimen, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF review indicates that the recollection was directly observed as required, document that the employee had another specimen with an invalid result for the same reason.

(3) Follow the recording and reporting procedures at (a)(4)(i) and (ii) of this section.

(4) If a negative result is required (i.e., pre-employment, return-to-duty, or follow-up tests), follow the procedures at § 40.160 for determining if there is clinical evidence that the individual is an illicit drug user.

(5) If the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

(f) If the employee's recollection (required at paragraph (a)(5) of this section) results in another invalid result for a different reason than that reported for the first specimen, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF review indicates that the recollection was directly observed as required, document that the employee had another specimen with an invalid result for a different reason.

(3) As the MRO, you should not contact the employee to discuss the result, but rather direct the DER to conduct an immediate recollection under direct observation without prior notification to the employee.

(4) If the CCF documentation indicates that the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

(g) If, as the MRO, you receive a laboratory invalid result in conjunction with a positive, adulterated, and/or substituted result and you verify any

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of those results as being a positive and/or refusal to test, you do not report the invalid result unless the split specimen fails to reconfirm the result(s) of the primary specimen.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35972, June 25, 2008]

§ 40.160 What does the MRO do when a valid test result cannot be produced and a negative result is required?

(a) If a valid test result cannot be produced and a negative result is required, (under § 40.159 (a)(5)(iii) and (e)(4)), as the MRO, you must determine if there is clinical evidence that the individual is currently an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation. In addition, if appropriate, you may also consult with the employee's physician to gather information you need to reach this determination.

(b) If you do not personally conduct the medical evaluation, as the MRO, you must ensure that one is conducted by a licensed physician acceptable to you.

(c) For purposes of this section, the MRO or the physician conducting the evaluation may conduct an alternative test (e.g., blood) as part of the medically appropriate procedures in determining clinical evidence of drug use.

(d) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report this to the employer as a negative test result with written notations regarding the medical examination. The report must also state why the medical examination was required (i.e., either the basis for the determination that a permanent or long-term medical condition exists or because the recollection under direct observation resulted in another invalid result for the same reason, as appropriate) and for the determination that no signs and symptoms of drug use exist.

(1) Check "Negative" (Step 6) on the CCF.

(2) Sign and date the CCF.

(e) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the employer as a cancelled test with written notations regarding the results of

the medical examination. The report must also state why the medical examination was required (i.e., either the basis for the determination that a permanent or long-term medical condition exists or because the recollection under direct observation resulted in another invalid result for the same reason, as appropriate) and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purpose of an actual negative test result (i.e., the employer is not authorized to allow the employee to begin or resume performing safety-sensitive functions, because a negative test result is needed for that purpose).

[73 FR 35972, June 25, 2008]

§ 40.161 What does the MRO do when a drug test specimen is rejected for testing?

As the MRO, when the laboratory reports that the specimen is rejected for testing (*e.g.*, because of a fatal or uncorrected flaw), you must do the following:

(a) Place a check mark in the "Test Cancelled" box (Step 6) on Copy 2 of the CCF and enter the reason on the "Remarks" line.

(b) Report to the DER that the test is cancelled and the reason for cancellation, and that no further action is required unless a negative test is required (*e.g.*, in the case of a pre-employment, return-to-duty, or follow-up test).

(c) You may only report a test cancelled because of a rejected for testing test result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

§ 40.162 What must MROs do with multiple verified results for the same testing event?

(a) If the testing event is one in which there was one specimen collection with multiple verified non-negative results, as the MRO, you must report them all to the DER. For example, if you verified the specimen as being positive for marijuana and cocaine and as being a refusal to test because the

specimen was also adulterated, as the MRO, you should report the positives and the refusal to the DER.

(b) If the testing event was one in which two separate specimen collections (*e.g.*, a specimen out of temperature range and the subsequent observed collection) were sent to the laboratory, as the MRO, you must:

(1) If both specimens were verified negative, report the result as negative.

(2) If either of the specimens was verified negative and the other was verified as one or more non-negative(s), report the non-negative result(s) only. For example, if you verified one specimen as negative and the other as a refusal to test because the second specimen was substituted, as the MRO you should report only the refusal to the DER.

(i) If the first specimen is reported as negative, but the result of the second specimen has not been reported by the laboratory, as the MRO, you should hold—not report—the result of the first specimen until the result of the second specimen is received.

(ii) If the first specimen is reported as non-negative, as the MRO, you should report the result immediately and not wait to receive the result of the second specimen.

(3) If both specimens were verified non-negative, report all of the non-negative results. For example, if you verified one specimen as positive and the other as a refusal to test because the specimen was adulterated, as the MRO, you should report the positive and the refusal results to the DER.

(c) As an exception to paragraphs (a) and (b) of this section, as the MRO, you must follow procedures at § 40.159(f) when any verified non-negative result is also invalid.

[73 FR 35972, June 25, 2008]

§ 40.163 How does the MRO report drug test results?

(a) As the MRO, it is your responsibility to report all drug test results to the employer.

(b) You may use a signed or stamped and dated legible photocopy of Copy 2 of the CCF to report test results.

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(c) If you do not report test results using Copy 2 of the CCF for this purpose, you must provide a written report (e.g., a letter) for each test result. This report must, as a minimum, include the following information:

(1) Full name, as indicated on the CCF, of the employee tested;

(2) Specimen ID number from the CCF and the donor SSN or employee ID number;

(3) Reason for the test, if indicated on the CCF (e.g., random, post-accident);

(4) Date of the collection;

(5) Date you received Copy 2 of the CCF;

(6) Result of the test (i.e., positive, negative, dilute, refusal to test, test cancelled) and the date the result was verified by the MRO;

(7) For verified positive tests, the drug(s)/metabolite(s) for which the test was positive;

(8) For cancelled tests, the reason for cancellation; and

(9) For refusals to test, the reason for the refusal determination (e.g., in the case of an adulterated test result, the name of the adulterant).

(d) As an exception to the reporting requirements of paragraph (b) and (c) of this section, the MRO may report negative results using an electronic data file.

(1) If you report negatives using an electronic data file, the report must contain, as a minimum, the information specified in paragraph (c) of this section, as applicable for negative test results.

(2) In addition, the report must contain your name, address, and phone number, the name of any person other than you reporting the results, and the date the electronic results report is released.

(e) You must retain a signed or stamped and dated copy of Copy 2 of the CCF in your records. If you do not use Copy 2 for reporting results, you must maintain a copy of the signed or stamped and dated letter in addition to the signed or stamped and dated Copy 2. If you use the electronic data file to report negatives, you must maintain a retrievable copy of that report in a format suitable for inspection and auditing by a DOT representative.

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(f) You must not use Copy 1 of the CCF to report drug test results.

(g) You must not provide quantitative values to the DER or C/TPA for drug or validity test results. However, you must provide the test information in your possession to a SAP who consults with you (see § 40.293(g)).

[66 FR 41952, Aug. 9, 2001]

§ 40.165 To whom does the MRO transmit reports of drug test results?

(a) As the MRO, you must report all drug test results to the DER, except in the circumstances provided for in § 40.345 .

(b) If the employer elects to receive reports of results through a C/TPA, acting as an intermediary as provided in § 40.345 , you must report the results through the designated C/TPA.

§ 40.167 How are MRO reports of drug results transmitted to the employer?

As the MRO or C/TPA who transmits drug test results to the employer, you must comply with the following requirements:

(a) You must report the results in a confidential manner.

(b) You must transmit to the DER on the same day the MRO verifies the result or the next business day all verified positive test results, results requiring an immediate collection under direct observation, adulterated or substituted specimen results, and other refusals to test.

(1) Direct telephone contact with the DER is the preferred method of immediate reporting. Follow up your phone call with appropriate documentation (see § 40.163).

(2) You are responsible for identifying yourself to the DER, and the DER must have a means to confirm your identification.

(3) The MRO's report that you transmit to the employer must contain all of the information required by § 40.163 .

(c) You must transmit the MRO's report(s) of verified tests to the DER so that the DER receives it within two days of verification by the MRO.

(1) You must fax, courier, mail, or electronically transmit a legible image or copy of either the signed or stamped

and dated Copy 2 or the written report (see § 40.163(b) and (c)).

(2) Negative results reported electronically (i.e., computer data file) do not require an image of Copy 2 or the written report.

(d) In transmitting test results, you or the C/TPA and the employer must ensure the security of the transmission and limit access to any transmission, storage, or retrieval systems.

(e) MRO reports are not subject to modification or change by anyone other than the MRO, as provided in § 40.149(c).

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001]

§ 40.169 Where is other information concerning the role of MROs and the verification process found in this regulation?

You can find more information concerning the role of MROs in several sections of this part:

§ 40.3—Definition.

§§ 40.47–40.49—Correction of form and kit errors.

§ 40.67—Role in direct observation and other atypical test situations.

§ 40.83—Laboratory handling of fatal and correctable flaws.

§ 40.97—Laboratory handling of test results and quantitative values.

§ 40.99—Authorization of longer laboratory retention of specimens.

§ 40.101—Relationship with laboratories; avoidance of conflicts of interest.

§ 40.105—Notification of discrepancies in blind specimen results.

§ 40.171—Request for test of split specimen.

§ 40.187—Action concerning split specimen test results.

§ 40.193—Role in “shy bladder” situations.

§ 40.195—Role in cancelling tests.

§§ 40.199–40.203—Documenting errors in tests.

§ 40.327—Confidentiality and release of information.

§ 40.347—Transfer of records.

§ 40.353—Relationships with service agents.

Subpart H—Split Specimen Tests

§ 40.171 How does an employee request a test of a split specimen?

(a) As an employee, when the MRO has notified you that you have a verified positive drug test and/or refusal to test because of adulteration or substitution, you have 72 hours from the time of notification to request a

test of the split specimen. The request may be verbal or in writing. If you make this request to the MRO within 72 hours, you trigger the requirements of this section for a test of the split specimen. There is no split specimen testing for an invalid result.

(b)(1) If, as an employee, you have not requested a test of the split specimen within 72 hours, you may present to the MRO information documenting that serious injury, illness, lack of actual notice of the verified test result, inability to contact the MRO (*e.g.*, there was no one in the MRO’s office and the answering machine was not working), or other circumstances unavoidably prevented you from making a timely request.

(2) As the MRO, if you conclude from the employee’s information that there was a legitimate reason for the employee’s failure to contact you within 72 hours, you must direct that the test of the split specimen take place, just as you would when there is a timely request.

(c) When the employee makes a timely request for a test of the split specimen under paragraphs (a) and (b) of this section, you must, as the MRO, immediately provide written notice to the laboratory that tested the primary specimen, directing the laboratory to forward the split specimen to a second HHS-certified laboratory. You must also document the date and time of the employee’s request.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35972, June 25, 2008]

§ 40.173 Who is responsible for paying for the test of a split specimen?

(a) As the employer, you are responsible for making sure (*e.g.*, by establishing appropriate accounts with laboratories for testing split specimens) that the MRO, first laboratory, and second laboratory perform the functions noted in §§ 40.175–40.185 in a timely manner, once the employee has made a timely request for a test of the split specimen.

(b) As the employer, you must not condition your compliance with these requirements on the employee’s direct payment to the MRO or laboratory or the employee’s agreement to reimburse