

Subpart G Medical Review Officers

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Subpart G - Medical Review Officers (MROs)

\$40.121 Who is qualified to act as an MRO?

You are qualified to act as an MRO in the DOT drug testing program only if you meet each of the following criteria: [40.33(b)]

(a) You are a licensed physician (Doctor of Medicine or Osteopathy). [40,33(b)(1)]

(b) You have knowledge of and clinical experience in controlled substances abuse: disorders, including detailed knowledge of alternative medical explanations for laboratory confirmed positive drug tests. [40.33(a)]

(c) You have working knowledge of laboratory results relating to adulterated and substituted specimens as well as the possible medical causes of specimens being unsuitable for testing. [new]

(d) You have a working knowledge of this part, the DOT MRO Guidelines, and the DOT agency regulation applicable to the employers for which you evaluate drug test results.

(e) You participate in and document training (e.g., a course) at least once every two years that relates directly to the MRO responsibilities of the DOT program, or self-certify that you have re-reviewed and understand this part and the applicable DOT guidelines. You must retain these records for two years. [new]

(f) If you were an MRO prior to the date these regulations are published, you must meet the requirements of paragraph (e) of this section by [date six months from the effective date of the final regulation]. If you become an MRO after [effective date of the final regulation], you must meet the requirements of paragraph (e) of this section prior to acting as an MRO. [new]

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

As an MRO, you have the following basic responsibilities: [new]

(a) You must act as an independent and impartial “gatekeeper” for the accuracy and integrity of the drug testing process.

(b) You must provide 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 canceled (see §§40.197 and 40.201);

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

(3) Reporting to the ODAPC or a relevant DOT agency any program issue for which you need

assistance in resolving.

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

(d) You must act to investigate and correct problems where possible, or notify appropriate parties (e.g., HHS/DWP, DOT/ODAPC, employers, service agents) where assistance is needed, (e.g., canceled or problematic **tests, incorrect results, problems with blind specimens**).

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

(f) You must protect the confidentiality of the testing process.

(g) 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?

(a) **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 for that employer. You may not derive any financial benefit by having an employer use a specific laboratory. **[parallel to laboratory]**

(b) **As** an MRO, you must maintain a statement for review by a DOT agency. The statement will certify that you do not have any financial or potentially conflicting relationship with any laboratory. **The** statement will remain in effect until its conditions change, at which time you must amend the statement to reflect current status. **[parallel to laboratory]**

§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 the result to the DER:

(a) Review Copy 4 of the CCF to determine if there are any errors in the chain of custody or elsewhere that may require you to cancel the test (see §§40.197, 40.199, and 40.201).

(1) Staff under your direct, personal supervision may conduct this administrative review for you (including the steps set forth in paragraphs (b) through (e) of this section), **but** only you can cancel a test. **[40.33(a)(2)]**

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

(i) You are required to personally review at least 10 percent of the CCFs reviewed by your staff on a quarterly basis, and take corrective action as necessary to ensure compliance with this part.

(ii) **You must** attest to **the** quality **assurance** review by initialing the CCFs which you reviewed.

(iii) You must mark these CCFs to make them easily identifiable for review by DOT agencies. **[new]**

(b) You may report a negative test result when you are in possession of a copy of Copy 2 or the original Copy 2 of the CCF, or you are in possession of the laboratory results report that conveys the negative laboratory test result. **In addition, you must have a copy of Copy 4 or the original Copy 4 of the CCF, or any copy of the CCF containing the employee's signature. [interp; new]**

(c) If the copy of the documentation provided to you by the laboratory appears unclear or erroneous, you must request that the laboratory send you an original or certified true copy. **[new]**

(d) On Copy 4 of the CCF, place a check mark in the "Negative" box in Step 8 and sign, initial, or stamp and date the verification statement. **[new]**

(e) Report the result directly to the DER in a confidential manner. **[DOT Letter 9-28-98; new]**

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

(a) As the MRO, you must do the following with respect to confirmed positive drug tests you receive from a laboratory, prior to verifying the result and releasing the result to the DER:

(1) Review the CCF to determine if there are any errors in the chain of custody or elsewhere that may require you to cancel the test (see §§40.197, 40.199, and 40.201). Staff under your direct, personal supervision may conduct this administrative review for you, but only you may cancel a test. **[40.33(a); interp]**

(2) If the copy of the documentation provided to you by the laboratory appears unclear or possibly erroneous, you must request that the laboratory send you an original or certified true copy. **[new]**

(3) 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. **[40.33 (c)(1)-(2)]**

(4) Verify the test result as either positive or negative, or cancel the test, consistent with the requirements of §§40.135 through 40.139. **[40.33(a)(2)]**

(5) **Report verified positive drug test results directly to the DER in a confidential manner, consistent with the requirements of §40.157. [new]**

(b) **You may only** report a positive test result when **you are in possession of a copy of Copy 2 or the original Copy 2 of the CCF. In addition, you must have a copy of Copy 4 or the original Copy 4 of the CCF, or any copy of the CCF containing the employee's signature. [interp; new]**

(c) Place a check mark in the "Positive" box in Step 8 on Copy 4 of the CCF, indicate the drug(s)/drug

metabolite(s) detected on the "Remarks" line, sign and date the verification statement, and report the result directly to the DER. [DOT Letter 9-28-98; new]

ALTERNATIVE 1 FOR PARAGRAPH (d)

(d) As the MRO, you must never inform the employer that you have received an employee's laboratory confirmed positive test result. You are prohibited from reporting any information to the DER or other persons 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 positive test result, and you must structure the way in which this information is received and stored to make sure that other personnel of the company do not have access to it. [interp]

ALTERNATIVE 2 FOR PARAGRAPH (d)

(d)(1) As the MRO, except as provided in paragraph (d)(2) of this section, you must never inform the employer that you have received an employee's laboratory confirmed positive test result. You are prohibited from reporting any information to the DER or other persons 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 positive test result, and you must structure the way in which this information is received and stored to make sure that other personnel of the company do not have access to it. [interp]

(2) If an employer has a stand-down policy that meets the requirements of §40.159(a), you may report to the DER that you have received an employee's laboratory confirmed positive laboratory test result. [new]

§40.131 How is the employee notified of the verification process after a confirmed positive test result?

(a) When, as the MRO, you receive a confirmed positive test result from the laboratory, along with the appropriate collection documentation (see Appendix C of this part), you must contact the employee directly, on a confidential basis, and 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. [40.33(c)(2)]

(b) As the MRO, staff under your personal supervision may conduct this initial contact for you. [40.33(c)(2)]

(1) This staff contact must be limited to explaining the consequences of the employee's declining to speak with you and scheduling the discussion between you and the employee.

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

(3) A staff person may advise an employee to have medical information ready to present at the interview with the MRO.

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

(c) **As the MRO, if you cannot reach the employee** directly after making reasonable efforts (at a minimum, two attempts) to reach the employee at the day and/or evening telephone numbers listed on the CCF over a period of at least 24 hours, you must:

(1) Document the efforts you made to contact the employee, including dates and times. **[new]**

(2) Contact the DER, instructing the DER to contact the employee. **[new; 40.33(c)(2)]**

(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 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. **[new]**

(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 contact the employee, you must document the date and time of the contact, and inform the MRO. **[40.33(c)(3)]**

(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. **[40.33(c)(4)]**

(i) Reasonable efforts include, as a minimum, two attempts to reach the employee at the day and/or evening telephone numbers listed on the CCF over a period of 24 hours. As the DER, you must document the dates and times of these efforts. **[new]**

(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) to contact the MRO and inform the MRO of the date and time of this attempted contact. **[new]**

940.133 Under what circumstances may the MRO verify a test as positive without interviewing the employee?

(a) As the MRO, you normally may verify a confirmed positive test result only after interviewing the **employee as provided in §§40.135 through 40.143**. However, **there are three circumstances in which** you may verify a confirmed positive test result (regardless of which drugs are involved) without such an interview: **[40.33(b)(3); (c)(5)]**

(1) You may verify a test result as positive if the employee expressly declines the opportunity to

discuss the test with you. Complete documentation of this occurrence must be made, including notation of informing, or attempting to inform, the employee of the consequences of not exercising the option to speak with the MRO. [40.33(c)(5)(i)]

(2) You may verify a test result as positive if neither you nor the DER, after making all reasonable efforts, has been able to contact the employee within 14 days of the date on which the MRO receives the confirmed positive test result from the laboratory. [40.33(c)(5)(ii)]

(3) You may verify a test result as positive if you or the DER has successfully made and documented a contact with the employee and instructed the employee to contact the MRO (see §40.131 (c) and (d)), **and more than 72 hours have passed since the time DER contacted the employee. [40.33(c)(5)(iii)]**

(b) As the MRO, when you verify a test result as positive under this section, you must document the date, time and reason. [new]

(c) As the MRO, if you verify a test result as positive under this section, you must allow the employee to present information to you documenting that serious illness, injury, or other circumstances unavoidably precluded contact with the MRO and/or DER in the times provided. [40.33(c)(6)]

(1) On the basis of such information, you may reopen the verification, allowing the employee to present information concerning a legitimate medical explanation for the confirmed positive test result.

(2) If you conclude that there is a legitimate medical explanation for the positive test result, you must change the verified result to negative, and report the change directly to the DER.

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

As the MRO, you must provide the following information to the employee at the beginning of the verification interview:

(a) You must tell the employee that the laboratory has determined that the employee's test result was positive. You must also tell the employee of the drugs for which his or her specimen tested positive. [new]

(b) You must explain the verification interview process to the employee, and that you will decide whether to verify the test result as positive based on information the employee provides in the interview. [new]

(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 drug test result. [new]

(d) You must tell the employee that you are authorized to provide to the employer, DOT, or another Federal safety agency any positive test result or medical information he or she provides during the interview under the circumstances stated in §40.327. This may include providing information to **employers concerning medication or medical conditions that could adversely affect the employee's safety-sensitive duties. [40.33(i)(2)]**

940.137 On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, and 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)/drug metabolite(s) in his or her system. **[40.33(a); (b)(3); (c)]**

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

(c) The employee has the burden of presenting evidence that a legitimate medical explanation exists. If you determine that there is such an explanation, you must verify the test result as negative. Otherwise, you must verify the test result as positive. **[interp]**

(d) In determining whether a legitimate medical explanation exists, you may consider the employee's use of a medication from a foreign country where it can be substantiated that the medication was legally obtained and used. **[interp]**

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

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

(a) If the laboratory detects the presence of 6-acetylmorphine (6-AM) in the specimen, you must verify the test result positive. **[40.33(d)]**

(b) In the absence of the 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 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 levels. **[new]**

(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 or codeine) **[40.33(d); new]**

(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: **[new, interp, MRO training materials]**

(i) Recent needle tracks;

(ii) Behavioral and psychological signs of acute opiate intoxication or withdrawal;

(iii) Clinical history of unauthorized use, such as an admission by the employee that an opiate drug was **ingested without legal authorization; or**

(iv) Use of a medication from a foreign country where it cannot be substantiated that the medication was legally obtained and legally used.

(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 to be conducted, a face-to-face interview with the employee.

(ii) No face-to-face interview is needed in establishing the clinical evidence referenced in paragraphs (c)(1)(iii) and (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 metabolite 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.)
[interp]

(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 and the employee does not state that he or she used opiates), 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. [interp]

\$40.141 How does the MRO obtain information for the verification decision?

As an MRO, you must do the following as you make the determinations needed for verification decision. [new]

(a) You must conduct a medical interview. You may review the employee's medical history and any **other relevant** biomedical factors. You may direct the employee to undergo further medical evaluation by you or another physician. [40.33(a); (b)(3); new]

(b) When the employee asserts that the presence of a drug(s)/drug metabolite(s) in his or her system results from taking prescription medication, you must review all medical records the employee provides. You may contact the employee's physician or other relevant medical personnel for further information. [40.33(b)(3); new]

(c) Before completing the verification process, and at your sole discretion, you may direct the laboratory to conduct a reanalysis of the primary specimen. (You may do so regardless of whether a single specimen or split specimen collection is involved.) You may choose the laboratory that tested

the primary specimen or another HHS-certified laboratory for this reanalysis. The purpose of this reanalysis is to gather further information concerning any questions you have about the technical or scientific validity of the laboratory's test. **[40.33(e)]**

\$40.143 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 obtained 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. **[40.33(b)(3); interp]**

(b) In reviewing the CCF, you must not consider evidence inessential to the documents in determining whether the test is valid. For example, you must review only what is on the face of the CCF for this purpose, not assertions by the employee that the CCF does not accurately reflect what happened at the collection site. **[new]**

(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 him as the subject of a random test, or directed him to take a reasonable suspicion or post-accident test without proper grounds under a DOT agency regulation, you must inform the employee that you cannot play a role in deciding these issues. **[interp]**

(d) It is not your function to consider explanations of confirmed positive 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 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. **[interp; MRO training materials]**

(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). **[interp]**

(f) You must never accept an assertion of consumption or other use of a hemp or other marijuana-related product as a basis for verifying a marijuana test negative. Consuming or using such a product is not a legitimate medical explanation. **[DOT guidance]**

\$40.145 How does the MRO notify employees of their right to a test of the split specimen or to a retest of a single specimen?

(a) You must notify the employee of procedures for requesting a retest of the specimen (single specimen collections) or a test of the split specimen (split specimen collections). The purpose of these tests is to determine whether drug(s)/drug metabolite(s) are present in the specimen tested.

(b) You must inform the employee that he or she has 72 hours to make a timely request for the additional test. [40.33(e)-(f)]

(c) You must tell the employee how to contact you in order to make a timely 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). [new]

(d) You must tell the employee that if he or she requests the additional test in a timely manner, 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) [new; interp]

(e) You must tell the employee that, when the test resulted from a split specimen collection, a retest of the primary specimen is not authorized. [40.33(e)-(f)]

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

940.147 What happens when a negative or positive test result is also dilute?

(a) As the MRO, when the laboratory reports that the specimen was dilute, you must report directly to the DER that, in addition to the specimen being negative or positive, the specimen was dilute and that the next time the employee is selected for a drug test the employer may require the specimen to be collected under direct observation. [DOT Letter 9-28-98; new]

(b) You must note that the specimen is dilute on the "Remarks" line in Step 8 on Copy 4 of the CCF. [DOT Letter 9-28-98; new]

(c) You may only report a dilute test result when you are in possession of a copy of Copy 2 or the original Copy 2 of the CCF. In addition, you must have a copy of Copy 4 or the original Copy 4 of the CCF, or any copy of the CCF containing the employee's signature. [interp; new]

§40.149 What happens when a test is not performed because of a fatal or uncorrected flaw?

(a) As the MRO, when the laboratory reports that a specimen test must be canceled because of a fatal or uncorrected flaw, you must place check marks in the "Test Not Performed" and "Test Canceled" boxes in Step 8 Copy 4 of the CCF and enter, "Fatal Flaw, "(with the flaw stated) or "Uncorrected Flaw, " (with the flaw stated), as appropriate, on the "Remarks" line. [DOT Letter 9-28-98; new]

(b) Report directly to the DER that the test is canceled, the reason for cancellation, and that no further action is required unless a negative test result is required (e.g., pre-employment, return-to-duty, follow-up). [DOT Letter 9-28-98; new]

(c) You may only report a fatal or uncorrected flaw test result when you are in possession of a copy of Copy 2 or the original Copy 2 of the CCF. In addition, you must have a copy of Copy 4 or the original Copy 4 of the CCF, or any copy of the CCF containing the employee's signature. [interp; new]

§40.151 What happens when a drug test specimen is unsuitable for testing?

(a) As the MRO, when the laboratory reports that the test result is "Test Not Performed – Specimen Unsuitable: Cannot obtain valid drug test result," you must do the following: [DOT Letter 9-28-98; new]

(1) Discuss the laboratory results with the certifying scientist to obtain more specific information.

(2) Contact the employee and inform the employee that the specimen was not suitable for testing or contained an unexplained interferant.

(3) After explaining the limits of disclosure (see §40.327), you should inquire as to medications the employee may have taken that may interfere with some immunoassay tests.

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

(i) Place check marks in the "Test Not Performed" and "Test Canceled" boxes in Step 8 on Copy 4 of the CCF and enter "Specimen Unsuitable: Cannot obtain valid drug test result" on the "Remarks" line.

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

(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 check marks in the "Test Not Performed" and "Test Canceled" boxes in Step 8 on Copy 4 of the CCF and enter "Specimen Unsuitable: Cannot obtain valid drug test result" on the "Remarks" line.

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

(b) You may only report an unsuitable for testing test result when you are in possession of a copy of **Copy 2 or the original Copy 2** of the CCF. In **addition, you must have a copy of Copy 4 or the original Copy 4** of the CCF, or any copy of the CCF containing the employee's signature. [interp; new]

(c) If the employee admits to having adulterated the specimen, you must follow procedures outlined in §40.153.

§40.153 What happens when a drug test specimen is adulterated or substituted?

(a) As the MRO, when the laboratory reports that the test result is "Test Not Performed – Specimen Adulterated/Substituted," you must do the following: **[DOT Letter 9-28-98; new]**

(1) Check the "Test Not Performed" box in Step 8 on Copy 4 of the CCF and enter "Adulterated," or "Substituted," and "Refusal to test" on the "Remarks" line.

(2) Report directly to the DER that the specimen was adulterated or substituted, either of which constitutes a refusal to test.

(3) Also, inform the DER that the employee has no right to have the split specimen tested (or to have a retest of a single specimen). You must not authorize a test of a split specimen or a retest of the primary specimen following an adulterated or substituted test result. The laboratory has already tested two aliquots of the primary specimen to confirm the accuracy of their result. **[Bernstein Letter 9/98; new]**

(b) You may only report an adulterated or substituted testing test result when you are in possession of a copy of Copy 2 or the original Copy 2 of the CCF. In addition, you must have a copy of Copy 4 or the original Copy 4 of the CCF, or any copy of the CCF containing the employee's signature. **[interp; new]**

§40.155 What happens when a drug test specimen is rejected for testing?

(a) As the MRO, when the laboratory reports that the test result is "Test Not Performed – Specimen Rejected for Testing," you must do the following: **[new]**

(1) Rule out collector error as the reason the specimen was rejected for testing. You may consult with the laboratory and must consult with the collection site in making this determination.

(2) If the rejection is a result of collector error, you must:

(i) Place check marks in the "Test Not Performed" and "Test Canceled" boxes in Step 8 on Copy 4 of the CCF and enter "Specimen Rejected for Testing: Collection Error _____" (with reason stated) on the "Remarks" line.

(ii) Report directly to the DER that the test is canceled, the reason for the cancellation, and that a second collection must take place immediately. This collection is not to be conducted under direct observation.

(3) If you determine that the rejection is not a result of collector error, you must:

(i) Place check marks in the "Test Not Performed" and "Test Canceled" boxes in Step 8 on Copy 4 of the CCF and enter "Specimen Rejected for Testing: _____" (with reason stated) on the "Remarks" line.

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

(b) You may only report a specimen rejected for testing test result when you are in possession of a copy of Copy 2 or the original Copy 2 of the CCF. In addition, you must have a copy of Copy 4 or the original Copy 4 of the CCF, or any copy of the CCF containing the employee's signature.

\$40.157 How does the MRO report test results to the employer?

As the MRO, you must report all drug test results (e.g., positive, negative, test not performed, canceled) directly to the DER in a confidential manner.

(a) You must make the reports and other communications concerning test results directly to the DER. **[alcohol parallel - 40.65(i)]**

(b) You must as expeditiously as possible, the same day preferably, report directly to the DER verified positive test results, results requiring an immediate collection under direct observation, and adulterated or substituted specimen results.

(1) Direct telephone contact with the DER is the preferred method of immediate reporting. **[alcohol parallel - 40.65(i)]**

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

(3) Your report shall contain all of the information in paragraph (c) of this section.

(c) In all cases, verified test results must be provided directly to the DER in writing. **The report must include the following information: [FMCSA - 49 CFR 382.407(a)(1) for all of paragraph (c)]**

(1) A statement that the test was conducted in accordance with this part;

(2) The full name, as indicated on the CCF, of the employee tested;

(3) The type of test as indicated on the CCF (e.g., random post-accident);

(4) The date and location of the collection;

(5) The identities of the persons or entities performing the collection, analyzing the specimen, and serving as the MRO for the test;

(6) The result of the test (e.g., positive, negative, test not performed, and canceled) and the date the result was verified; and

(7) For verified positive tests, the substance for which the test was positive.

(d) Within three days of your verification of the result, you must provide the DER the signed, written report of the verified test result.

(1) For any result (positive, negative, test not performed, or canceled), you may use Copy 4 of the CCF or a legible photocopy of it. If you provide a written report to the employer using any means other than Copy 4, you must retain a signed (for positive, test not performed, or canceled tests) or stamped (for a negative test) Copy 4 in your records.

(2) For a negative test, if you do not use Copy 4 of the CCF or a legible photocopy of it, you may use such means as a letter listing negative results for a group of specimens, each identified by its specimen ID number, or an individual letter providing each test result.

(3) You must not use Copy 1 or Copy 2 to report negative drug test results. Your signature must be on the report; you may sign or rubber-stamp the report of the result (or a staff member can rubber-stamp it for you with your written authorization). You may not use electronic signatures for this purpose.

(4) For a positive test, you must make sure that your signature and the substance(s) for which the test was positive are legibly noted in Step 8 of the CCF. You must sign the report; rubber stamps are not acceptable. You may not use electronic signatures for this purpose.

(5) For a test not performed or for a canceled test, you must make sure that your signature and the required explanation(s) for the result are legibly noted in Step 8 of the CCF. You must sign the report; rubber stamps are not acceptable. **You may not use electronic signatures for this purpose. [new]**

540.159 When MROs send reports of positive, dilute, unsuitable, substituted, or adulterated test results to employers, what is an employer to do?

ALTERNATIVE 1 FOR PARAGRAPH (a)

(a) **As** an employer, you must never take any personnel or disciplinary action, permanent or temporary, related to a DOT drug test (including removing the employee from safety-sensitive functions) before receiving a verified positive test result from the MRO. Specifically, you are prohibited from standing-down an employee on the basis of information or belief that the employee has a laboratory confirmed positive drug test result. You may, however, temporarily medically disqualify an employee in the circumstances spelled out in §40.13 l(d)(2). **[§40.33(a)(1); interp; new]**

ALTERNATIVE 2 FOR PARAGRAPH (a)

(a) As an employer, you must never take any permanent personnel or disciplinary action, related to a DOT drug test, before receiving a verified positive drug test result from the MRO.

(1) However, you may stand-down an employee (i.e., temporarily remove the employee from the performance of safety-sensitive functions) after your DER is informed by the MRO that the individual has a laboratory confirmed positive drug test result, pending the completion of the MRO's verification process.

(2) If you choose to stand-down an employee, you must ensure that information about the laboratory confirmed positive test result or the reason for the employee's temporary removal from performance of safety-sensitive functions is not made available by the MRO or DER to any other employees of your organization or other persons.

(3) If the MRO reports to you that the test has been verified negative or has been canceled, you must **immediately** return the employee to the performance of safety-sensitive duties, without any **adverse** consequences to the employee and with no notation of the stand-down or the laboratory confirmed positive test result retained in any records pertaining to the employee. You may also temporarily medically disqualify an employee in the circumstances referenced in §40.13 l(d)(2). **[§40.33(a)(1); interp; new]**

(b) As an employer who receives a **verified** positive test result from the MRO, you must immediately remove the employee involved from performing safety sensitive functions. You must take this action upon receiving the **initial report** from the MRO. Do not wait to receive the written report or the result of a split specimen test. **[new]**

(c) As an employer who receives a test result from the MRO indicating that the employee's specimen was adulterated or substituted, you must consider this a refusal to test and immediately remove the employee involved from performing safety sensitive functions. You must take this action on receiving the initial report from the MRO. Do not wait to receive the written report. **[DOT Letter 9-28-98; new]**

(d) As an employer who receives a test result from the MRO indicating that the employee's specimen was dilute, the next time the employee is selected for a drug testing, you may require the specimen to be collected under direct observation. **[DOT Letter 9-28-98]**

(e) As an employer who receives a test result from the MRO indicating that the employee's *specimen* was unsuitable for testing or rejected for testing and that a second collection must take place under **direct** observation –

(1) You must immediately direct the employee to provide a new specimen under direct observation.

(2) You must not attach consequences to the finding of unsuitability other than collecting a new specimen under direct observation.

(3) You must not give any advance notice of this test requirement to the employee and can only notify the employee immediately before the collection.

(4) You must instruct the collector to note on the CCF the same reason (e.g. random test, post-accident test) as for the original collection. **[DOT Letter 9-28-98; new]**

(f) As an employer who receives a canceled test result when a negative result is required (e.g., **pre**-employment, return-to-duty, or follow-up test), you must direct the employee to provide another specimen. **[DOT Letter 9-28-98; new]**

(g) As an employer, you may also be required to take additional actions required by DOT agency regulations (e.g., FM requires some positive drug tests to be reported to the Federal Air Surgeon).

§40.161 May the employer or MRO change a verified drug test result?

(a) As the employer, you must not change a test result that you have received from the MRO. **[interp]**

(b) As the MRO, you may change a verified drug test result only in the following situations: [new]

(1) When you have reopened a verification that was done without an interview with an employee, as in §40.133(c).

(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 you receive, within 60 days of the original verification decision, 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)/ drug **metabolite(s)** in the employee's specimen. For example, **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)/drug **metabolite(s)** in the employee's specimen. If you receive the information after the 60 day **period, you must consult with ODAPC prior to changing the result.**

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

(c) As the MRO, in any case where you change a result, you must **notify** the DER of the changed result as provided in 940.157. **[new]**

§40.163 Where is other information concerning the role of MROs found in this regulation?

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

§40.3 - definition.

§40.67 ▪ role in direct observation and other atypical test situations.

§40.83 - corrective actions in atypical test situations.

940.95 ▪ receipt of laboratory reports.

§40.99 ▪ authorization of longer laboratory retention of specimens.

\$40.101 ▪ relationship with laboratories; avoidance of conflicts of interest.

\$40.107 ▪ notification of laboratory errors.

\$40.171 - request for test of split specimen.

\$40.183 - action concerning split specimen test results.

\$40.191 ▪ role in “shy bladder” situations.

\$40.193 ▪ role in canceling tests.

§§40.199 ▪ 40.203 ▪ documenting errors in tests.

\$40.325 ▪ transfer of records.

\$40.327 ▪ confidentiality and release of information.

\$40.329 ▪ providing information to other employers.

\$40.35 1 ▪ relationships with service agents.