

PART 40 QUESTIONS AND ANSWERS

The Office of General Counsel and Office of Drug and Alcohol Policy and Compliance of the Department of Transportation are providing these questions and answers. They constitute official and authoritative guidance and interpretation concerning 49 CFR Part 40 (see 49 CFR 40.5).

These Questions and Answers are dated 07/08.

QUESTION:

During periods of hot weather, how may Medical Review Officers (MROs) handle laboratory results reported as invalid because of pH greater than or equal to 9.0 but less than or equal to 9.5?

ANSWER:

- Part 40 requires an MRO to provide an employee the opportunity to present a medical explanation for an invalid test result, to include any related to pH.
 - If the employee provides an acceptable medical explanation, the MRO is authorized to cancel the test and take no further action.
 - If there is no acceptable medical explanation, the MRO will cancel the test and will notify the employer or Designated Employer Representative (DER) to direct another collection under direct observation.
- The Department is aware of current research and studies offering evidence that, over time, heat may cause the pH to rise, typically into the range of 9.0 through 9.3, but not higher than 9.5. [See, for example, “Urine pH: the Effects of Time and Temperature after Collection,” Journal of Analytical Toxicology, Vol. 31, October 2007.]
- Consequently, when an employee has no other medical explanation for the pH in the 9.0 - 9.5 range, MROs should consider whether there is evidence of elapsed time and increased temperature that could account for the pH value.
- In doing so, MROs are authorized to consider the following:
 - The temperature conditions that were likely to have existed between the time of collection and transportation of the specimen to the laboratory; and
 - The length of time between the specimen collection and arrival at the laboratory.
- MROs may talk with the collection sites to discuss time and temperature issues, including any pertinent information regarding specimen storage.
- If the MRO determines that time and temperature account for the pH value, the MRO is authorized to cancel the test and take no further action.
- If the MRO determines that time and temperature fail to account for the pH value, the MRO is authorized cancel the test and direct another collection under direct observation.

QUESTION:

Are there any circumstances for which an employee should be given more than 3 hours and 40 ounces of fluids to provide a sufficient amount of urine during a collection?

ANSWER:

- No. The Department sees no situations for which an employee should be given more than 3 hours and offered more than 40 ounces of fluids to provide a sufficient amount of urine after the “first unsuccessful attempt” to do so [see §40.193(b)(4)].
- The Department regards the “first unsuccessful attempt” to be very first time the employee comes out of the urination area with less than 45 mL of urine.
- This is true about the “first unsuccessful attempt” even if a subsequent attempt during the three-hour period requires an immediate collection under direct observation because the specimen is outside the appropriate temperature range or shows signs of tampering [see §40.65(b)&(c)].
- For example: An employee presents an insufficient amount of urine at noon and is urged by the collector to drink up to 40 ounces of fluid distributed through a period of up to 3 hours (3 o’clock, in this example).
 - At 2 o’clock, the employee indicates that he or she can now provide the specimen, enters the collection area, but returns with a specimen outside the acceptable temperature range.
 - The collector immediately conducts an observed collection, but the employee – for the second time during this collection event, which began at noon – provides less than 45 mL of urine.
 - The employee has up to 3 o’clock and any remaining fluids to provide an adequate amount of urine under direct observation: The employee is not given an additional three hours and is not offered an additional 40 ounces of fluids.
 - If the employee ultimately fails to provide a sufficient amount of urine during the remaining time, the collector discontinues the collection, discards any specimen the employee previously provided, appropriately documents the CCF, and immediately notifies the DER and the MRO – following the requirements at §40.193(b)(4) and (b)(5).

QUESTION:

Must a test result be cancelled by the MRO when it is discovered the employee did not have a full three hours to provide a sufficient amount of urine?

ANSWER:

- Not affording the employee a full three hours to provide a specimen is not automatically a basis for the MRO to cancel a test.
- The three hour time period is a maximum rather a minimum. But, to avoid potential issues about the fairness of the collection, collectors are advised to provide the full three hours.
- In each of the following examples, the collector could stop the collection process, thoroughly document the details and times on Copy 2 of the CCF, and inform the DER of the employee's inability to provide a sufficient amount of urine:
 - After 2 hours and 50 minutes, the employee informs the collector there is no reason to try again because he or she will not be able to provide a specimen. The collector terminates the collection.
 - After 2 hours and 50 minutes, the employee requests to try again but provides another insufficient amount of urine. The collector terminates the collection because there is no practical possibility that the employee will provide the requisite amount in the next 10 minutes.
- In each of these two examples, the employee has had a fair opportunity to provide 45 mL of urine, and the test should not be cancelled because the full three-hour period was not used.
- The medical evaluation should be conducted to determine if there is a legitimate physiological condition or psychological disorder explanation for the employee's inability to provide the requisite amount of urine.
- In situations where it appears the employee was not provided a fair opportunity to provide the requisite amount of urine, the MRO could cancel the test.
 - For example, the collector terminates a collection after two hours because the collection site is closing and all collectors are leaving.
- Please note that it remains a refusal to test if the employee leaves the collection site without permission.

QUESTION:

In addition to information needed for billing purposes, does DOT authorize other information to be included outside the boundaries of the Alcohol Testing Form (ATF)?

ANSWER:

- Yes. For record storage, tracking, and retrieval purposes, the DOT will permit other information, such as barcodes and tracking numbers, to be affixed or printed on the ATF.