American College of Occupational and Environmental Medicine

Submitted via Regulations.gov

October 29, 2026

Douglas Simon
Director
Office of Drug and Alcohol Policy and Compliance
U.S. Department of Transportation
1200 New Jersey Avenue SE
Washington, DC 20590

Re: Docket No. DOT-OST-2026-3664 — Petition for Rulemaking; Invalid Specimen Determinations

Dear Mr. Simon:

The American College of Occupational and Environmental Medicine (ACOEM) appreciates the opportunity to comment on the Department of Transportation's (DOT) notification of the petition for rulemaking concerning invalid specimen determinations under 49 CFR part 40. ACOEM represents physicians and other health professionals dedicated to the health and safety of workers, workplaces, and the public. Occupational medicine physicians, including Medical Review Officers (MROs), have extensive experience applying the federal drug and alcohol testing regulations in safety-sensitive work.

ACOEM supports fair, medically sound, individualized review when an employee presents a legitimate medical explanation relevant to an invalid specimen or an inability to provide a sufficient specimen. At the same time, federally regulated testing must preserve specimen integrity, timely recollection, consistent application of scientifically established specimen-validity standards, and the public-safety purposes of Part 40.

After review of the petition, ACOEM recommends that DOT not grant the petition in its present form. The petition identifies issues that merit continued attention and, where appropriate, clarification through guidance or MRO education. However, the proposed amendments risk conflating two medically and procedurally distinct situations: (1) MRO review of an invalid specimen and abnormal specimen-validity findings, and (2) evaluation of an employee who cannot provide a sufficient urine specimen. Existing Part 40 provisions already contain medical-review mechanisms for both circumstances. ACOEM believes targeted clarification would be preferable to creating a new overlapping regulatory process.

1. Invalid specimen review and insufficient-specimen evaluation should remain distinct.

The petition proposes additions to §40.193 while also addressing abnormal specimen-validity findings, including abnormal pH. DOT itself notes in the published notice that §40.193 addresses failure to provide a sufficient specimen, while §40.159 is the provision addressing what an MRO does when a drug test result is invalid.

That distinction is substantive, not merely organizational. An abnormal specimen-validity result concerns the characteristics and integrity of a specimen that has been produced and tested. Paruresis or another voiding disorder concerns the employee's ability to provide a specimen. A voiding disorder, standing alone, does not medically explain the presence of an interfering substance, abnormal physical characteristic, endogenous substance at an abnormal concentration, or an adulterant in a specimen that was successfully provided.

ACOEM therefore recommends that DOT preserve a clear separation between §40.159 invalid-specimen determinations and §40.193 insufficient-specimen/shy-bladder evaluations. Any future guidance should explicitly distinguish these pathways.

2. Part 40 already provides an opportunity for medical review.

The petition states that the current framework does not require a structured medical verification opportunity when an employee asserts a legitimate medical explanation. ACOEM agrees that consistency and transparency are important, but the existing regulatory framework already assigns the MRO a central medical-review function.

Under §40.159, the MRO evaluates invalid results and determines whether an acceptable medical explanation exists. Section 40.193 separately establishes a medical evaluation process when an employee is unable to provide a sufficient specimen. These provisions reflect the MRO's role as an independent physician, trained and certified with periodic mandated and updated training based upon DOT criteria, applying medical judgment within a forensic testing program.

Before creating an additional process, ACOEM recommends that DOT determine whether there is evidence of a material, recurrent problem under the existing rules. Useful information would include the number and type of invalid specimens for which medical explanations are asserted; the frequency with which such explanations alter the MRO determination; the frequency of §40.193 evaluations involving documented voiding disorders; and evidence that legitimate medical conditions are being systematically overlooked.

3. ACOEM does not support an automatic 72-hour delay before directly observed recollection.

The petition would require an MRO to provide a period of up to 72 hours for documentation when an employee asserts a "plausible medical explanation" for an abnormal specimen-

validity finding and would require a written determination before directing the observed recollection.

ACOEM is concerned that an automatic delay based on an assertion of medical plausibility could impair the forensic value of recollection. Timeliness is an important component of drug testing. A delay can increase the interval from the original collection and may reduce the ability of a subsequent test to identify drug use occurring near the time of the first. In the current regulations, any indicated recollection is to be done with minimal advance notice and as soon as feasible.

An employee should be permitted to provide relevant medical information, and the MRO should consider information that is timely, credible, and medically relevant. However, the mere assertion of a "plausible" explanation should not automatically stay an otherwise required recollection. The MRO should retain discretion to obtain additional information when necessary, without creating a mandatory delay that applies to every asserted medical explanation.

4. "Plausible medical explanation" is not an appropriate regulatory threshold.

The term "plausible" is undefined and potentially much broader than a medically adequate explanation. In a forensic testing program, the relevant question is not simply whether a medical condition could be imagined as related to a finding. The MRO must determine whether the available medical evidence provides an adequate explanation for the specific laboratory or collection circumstance at issue.

ACOEM recommends retaining the existing emphasis on the MRO's reasonable medical judgment and an adequate or legitimate medical explanation. If DOT concludes that greater consistency is needed, ACOEM would support guidance describing the types of clinical information that may be relevant while avoiding a rigid evidentiary checklist.

5. Specimen-validity standards should remain grounded in HHS/SAMHSA laboratory science.

The petition requests defined evaluation standards for abnormal urinary chemistry. ACOEM cautions against creating a parallel clinical pathway that could inadvertently override or dilute established federal specimen-validity criteria.

Laboratory validity thresholds serve a forensic and analytical purpose. Clinical diagnoses, medications, collection circumstances, transport, storage, and other medically or scientifically relevant information may appropriately be considered where Part 40 permits such review, but abnormal laboratory findings should not be reclassified merely because a medical condition is asserted.

Any regulatory change involving specimen-validity thresholds or interpretation of abnormal urinary chemistry should be developed in coordination with the U.S. Department of Health and Human Services (HHS) and the Substance Abuse and Mental Health Services

Administration (SAMHSA) so that DOT requirements remain aligned with federal laboratory science and Mandatory Guidelines.

6. ACOEM recognizes paruresis, but a diagnosis should not automatically excuse an observed collection or establish inability to provide a specimen.

ACOEM recognizes that paruresis (psychogenic urinary retention) and other medically documented voiding disorders can be genuine clinical conditions. Employees with such conditions should receive appropriate individualized consideration under Part 40.

However, the existence of a diagnosis and the causation question presented by a particular collection are not identical. The relevant determination is whether an ascertainable physiologic condition or medically documented pre-existing psychological disorder actually prevented, or with the degree of probability required by the regulation could have prevented, the employee from providing the required specimen under the circumstances at issue.

ACOEM therefore recommends against any regulatory language that would make a diagnosis of paruresis, by itself, sufficient to avoid directly observed collection or a refusal determination. The existing individualized medical evaluation process is better suited to that determination.

7. Mandatory specialist consultation is unnecessary; consultation should remain within MRO medical judgment.

The petition would require the MRO to consider consultation with a urologist or mental health professional when certain diagnoses are asserted. ACOEM supports specialty consultation when the MRO determines that the medical question cannot be adequately resolved without it.

However, Part 40 should not create an expectation that specialist consultation is routinely necessary whenever a donor asserts a urologic or functional voiding disorder. MROs are licensed physicians with specific training in the federal testing process. A regulatory specialist-consultation requirement could add delay, cost, and uncertainty without improving the quality of most determinations.

ACOEM recommends preserving MRO discretion to seek consultation when clinically necessary and preserving the existing physician-evaluation mechanisms applicable to insufficient-specimen cases.

8. Concise documentation of consequential MRO decisions may be reasonable, but a new quasi-adjudicatory process is not necessary.

ACOEM supports appropriate documentation of the information considered and the basis for significant MRO determinations. Such documentation promotes continuity, quality assurance, and defensibility.

ACOEM would not support a requirement that MROs generate lengthy written opinions to employees before every observed recollection. Such a requirement could transform a time-sensitive medical review process into an adjudicatory proceeding and delay testing. If DOT determines that documentation requirements should be clarified, ACOEM recommends a concise record in the MRO's case documentation identifying the relevant information considered and the regulatory basis for the determination.

ACOEM Recommendations

- Do not grant the petition as drafted.
- Maintain the distinction between §40.159 invalid-specimen review and §40.193 insufficient-specimen/shy-bladder evaluation.
- Do not impose an automatic 72-hour delay in a required directly observed recollection solely because an employee asserts a plausible medical explanation.
- Do not adopt "plausible medical explanation" as a new regulatory threshold; retain meaningful MRO medical judgment regarding whether an adequate medical explanation exists.
- Preserve established HHS/SAMHSA specimen-validity science and coordinate any changes concerning urinary chemistry or laboratory thresholds with HHS/SAMHSA.
- Recognize medically documented paruresis and other voiding disorders through individualized evaluation, without treating the diagnosis alone as an automatic exemption from observed collection or as proof that a refusal determination is inappropriate.
- Keep specialty consultation discretionary when medically indicated rather than creating a routine regulatory expectation.
- If DOT identifies a need for greater consistency, address it first through targeted guidance, MRO education, and concise documentation expectations rather than an additional overlapping regulatory pathway.
- Before initiating rulemaking, obtain and evaluate data demonstrating the frequency and nature of the asserted problem and whether existing Part 40 protections are failing in practice.

Conclusion

ACOEM shares the petitioner's objective of ensuring that legitimate medical conditions receive fair and competent consideration. The integrity of the DOT testing program, however, depends on both medical fairness and a timely, scientifically sound forensic process.

The existing Part 40 framework already places medical judgment with the MRO and provides distinct pathways for invalid specimens and insufficient specimens. ACOEM recommends strengthening clarity and consistency within those existing pathways rather than creating a new 72-hour medical-verification process that could delay recollection, blur distinct medical questions, and create unnecessary procedural complexity.

ACOEM appreciates DOT's consideration of these comments and would welcome the opportunity to provide additional clinical and MRO expertise as the Department evaluates the petition.

Sincerely,



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President
American College of Occupational and Environmental Medicine

Authorities and Source Materials for Final Review

- U.S. Department of Transportation, Petition for Rulemaking; Notification of Petition for Rulemaking; Invalid Specimen Determinations, Docket No. DOT-OST-2026-3664, published Oct. 1, 2026.
- 49 C.F.R. § 40.159, What does the MRO do when a drug test result is invalid?
- 49 C.F.R. § 40.193, What happens when an employee does not provide a sufficient amount of specimen for a drug test?
- 49 C.F.R. § 40.67, When and how is a directly observed urine collection conducted?
- Applicable HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs and SAMHSA specimen-validity guidance.