

The Department of Transportation (DOT) issued major changes to its CFR 49 Part 40 Regulations today, June 25, 2008. This is a final rule change and becomes effective August 25, 2008. The DOT amended certain provisions to change instructions to collectors, laboratories, medical review officers, and employers regarding adulterated, substituted, diluted, and invalid urine specimen results. This Final Rule makes specimen validity testing mandatory within regulated transportation industries.

In addition, a number of changes were made concerning procedures for direct observed collections:

1. This Final Rule makes it mandatory for laboratories to test all DOT specimens for specimen validity (i.e., adulterants and urine substitutes) and for laboratories to follow all Department of Health and Human Services (HHS) protocols for doing so.
2. During observed collections, items such as prosthetic devices designed to carry clean urine will be checked for by observers with both male and female donors. The observer will have the employee raise and lower clothing, and then put it back into place for the observed collection.
3. Observed collections will now be required, rather than optional, for all return-to-duty and follow-up drug testing.
4. In an effort to thwart those who would manufacturer products designed to adulterate specimens, the Final Rule will no longer have easy-to-follow tables and charts outlining the adulterants for which laboratories are testing and the scientific cutoff levels at which laboratories are testing them.
5. Definitions in the Final Rule have been changed to harmonize with the Health & Human Services.
6. The following occurrences are now considered a refusal to test:
  - a. The donor is found to possess or wear a prosthetic or other device that could be used to interfere with the collection process,
  - b. The donor refused to follow collector instructions during an observed collection process to raise and lower clothing as specified in regulations, and
  - c. The donor admits to the collector or MRO that he/she adulterated or substituted the specimen.
7. The Final Rule will close the potentially endless loop on invalid specimen results; and employees requiring negative results [for example, pre-employment tests], when they have medical reasons for providing invalid results, will be able to obtain them through medical evaluations to rule out signs and symptoms of drug use.
8. The Final Rule will streamline and simplify the potential myriad of complicated laboratory-confirmed and MRO-verified drug test results.
9. The Final Rule requires drug-testing laboratories to report to DOT semi-annual statistical summaries on all of their DOT testing.