

## DOT REVISIONS TO 49 CFR PART 40

### EFFECTIVE AUGUST 25, 2008

The US Department of Transportation (DOT) issued a final rule on June 25, 2008 making significant changes to 49 CFR Part 40 in the procedures governing specimen validity testing (SVT), direct observation specimen collections, review and reporting of invalid test results, and refusal to test determinations. In large part the changes to Part 40 are intended to harmonize the DOT workplace testing procedures with what was earlier published by the US Department of Human Services (DHHS) in the Mandatory Guidelines for Federal Workplace Testing Programs.

The significant revisions to the DOT rule are:

1. **Specimen validity testing (SVT) must be conducted by the drug testing laboratory on every DOT specimen.** This means that the laboratory must: determine the creatinine concentration (and if the creatinine concentration is less than 20 mg/dL, must also determine the specific gravity of the specimen); determine the pH of the specimen; and perform one or more tests for oxidizing agents.
2. **The DOT has adopted the DHHS criteria for laboratories in reporting invalid specimens.** There are 12 circumstances when the laboratory must report the result to the MRO as an invalid specimen. When the laboratory reports a result as invalid, the MRO will discuss the laboratory findings with a laboratory certifying scientist; determine if further testing at another drug testing laboratory is appropriate and, if not; contact the specimen donor and conduct an interview to determine if there is a medical explanation for the specimen's invalidity.
3. **Direct Observation collections include additional procedures to deter and detect the use of prosthetic devices for urine adulteration and substitution.** The observer in a direct observation collection must require the specimen donor to demonstrate that they are not wearing or using a specimen adulteration or substitution device by visually inspecting the donor's body (front and back) without clothing from the chest line to the knees. Once the observer has performed the visual inspection, the donor may re-position clothing (e.g. shirt, blouse, pants, trousers, etc.), and the observer must maintain visual observance of the urine being voided directly into the collection container. A donor's refusal to comply with the collector/observer's instructions is a refusal to test. The observer must always be the same gender as the donor, however does not have to be a trained/qualified collector.

4. **MRO verification procedures for multiple laboratory results on a specimen, multiple results for a specimen collection where 2 specimens were collected (i.e. the first specimen is “suspect” and a second specimen was collected under direct observation), and invalid results on successive specimen collections have been revised and clarified.** Essentially, the MRO reporting categories for test results remain unchanged: MROs will report results to employers as negative (negative dilute), positive (drug(s) identified), cancelled (reason for cancelled test provided), and refusal to test (adulterated, substituted, no medical explanation for shy bladder).

5. **The revisions to Part 40 emphasize in several sections the requirement for employers to ensure that immediate re-collections of specimens under direct observation procedures take place.** When the MRO directs the employer to conduct such a recollection, the employer must ensure that the donor does not have advance notice of collection, and must ensure that the collector knows that the collection is to be directly observed. The rule now provides for the MRO to order an additional re-collection if he/she discovers that the previous collection was not directly observed when it was required to do so.

These revisions to Part 40 are effective August 25, 2008. Thus, employers should review their policies and procedures to reflect actions they will take on employees whose specimens are reported as adulterated and substituted; to identify requirements for direct observation of certain specimen collections; and to update definitions in their documents to make them consistent with the DOT rule. The DOT Final Rule is available at the DOT website [www.dot.gov/ost/dapc](http://www.dot.gov/ost/dapc).

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