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AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

SOURCE: 65 FR 79526, Dec. 19, 2000, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 40 appear at 73 FR 33329, June 12, 2008.

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Subpart A—Administrative Provisions

§ 40.1 Who does this regulation cover?

(a) This part tells all parties who conduct drug and alcohol tests required by Department of Transportation (DOT) agency regulations how to conduct these tests and what procedures to use.

(b) This part concerns the activities of transportation employers, safety-sensitive transportation employees (including self-employed individuals, contractors and volunteers as covered by DOT agency regulations), and service agents.

(c) Nothing in this part is intended to supersede or conflict with the implementation of the Federal Railroad Administration's post-accident testing program (see 49 CFR 219.200).

§ 40.3 What do the terms used in this part mean?

In this part, the terms listed in this section have the following meanings:

Adulterated specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

Affiliate. Persons are affiliates of one another if, directly or indirectly, one controls or has the power to control the other, or a third party controls or has the power to control both. Indicators of control include, but are not limited to: interlocking management or ownership; shared interest among family members; shared facilities or equipment; or common use of employees. Following the issuance of a public interest exclusion, an organization having the same or similar management, ownership, or principal employees as the service agent concerning whom a public interest exclusion is in effect is regarded as an affiliate. This definition is used in connection with the public interest exclusion procedures of Subpart R of this part.

Air blank. In evidential breath testing devices (EBTs) using gas chromatography technology, a reading of the device's internal standard. In all other

EBTs, a reading of ambient air containing no alcohol.

Alcohol. The intoxicating agent in beverage alcohol, ethyl alcohol or other low molecular weight alcohols, including methyl or isopropyl alcohol.

Alcohol concentration. The alcohol in a volume of breath expressed in terms of grams of alcohol per 210 liters of breath as indicated by a breath test under this part.

Alcohol confirmation test. A subsequent test using an EBT, following a screening test with a result of 0.02 or greater, that provides quantitative data about the alcohol concentration.

Alcohol screening device (ASD). A breath or saliva device, other than an EBT, that is approved by the National Highway Traffic Safety Administration (NHTSA) and appears on ODAPC's Web page for "Approved Screening Devices to Measure Alcohol in Bodily Fluids" because it conforms to the model specifications from NHTSA.

Alcohol screening test. An analytic procedure to determine whether an employee may have a prohibited concentration of alcohol in a breath or saliva specimen.

Alcohol testing site. A place selected by the employer where employees present themselves for the purpose of providing breath or saliva for an alcohol test.

Alcohol use. The drinking or swallowing of any beverage, liquid mixture or preparation (including any medication), containing alcohol.

Aliquot. A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen.

Alternate specimen. An authorized specimen, other than the type of specimen previously collected or attempted to be collected.

Breath Alcohol Technician (BAT). A person who instructs and assists employees in the alcohol testing process and operates an evidential breath testing device.

Cancelled test. A drug or alcohol test that has a problem identified that cannot be or has not been corrected, or which this part otherwise requires to be cancelled. A cancelled test is neither a positive nor a negative test.

Chain of custody. The procedure used to document the handling of the urine specimen from the time the employee gives the specimen to the collector until the specimen is destroyed. This procedure uses the Federal Drug Testing Custody and Control Form (CCF) as approved by the Office of Management and Budget.

Collection container. A container used to collect a specimen.

Collection site. A place selected by the employer where employees present themselves for the purpose of providing a specimen for a drug test.

Collector. A person who instructs and assists employees at a collection site, who receives and makes an initial inspection of the specimen provided by those employees, and who initiates and completes the CCF.

Commercial Driver's License Drug and Alcohol Clearinghouse (Clearinghouse). A database, administered by the Federal Motor Carrier Safety Administration, containing records of commercial motor vehicle drivers' violations of controlled substances and alcohol testing program requirements, as set forth in part 382 of this title, as well as their return-to-duty status.

Confirmatory drug test. A second analytical procedure performed on a different aliquot of the original specimen to identify and quantify a specific drug or drug metabolite.

Confirmatory validity test. A second test performed on a different aliquot of the original urine specimen to further support a validity test result.

Confirmed drug test. A confirmation test result received by an MRO from a laboratory.

Consortium/Third-party administrator (C/TPA). A service agent that provides or coordinates the provision of a variety of drug and alcohol testing services to employers. C/TPAs typically perform administrative tasks concerning the operation of the employers' drug and alcohol testing programs. This term includes, but is not limited to, groups of employers who join together to administer, as a single entity, the DOT drug and alcohol testing programs of its members. C/TPAs are not "employers" for purposes of this part.

Continuing education. Training for substance abuse professionals (SAPs)

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who have completed qualification training and are performing SAP functions, designed to keep SAPs current on changes and developments in the DOT drug and alcohol testing program.

Cutoff. The analytical value (*e.g.*, drug or drug metabolite concentration) used as the decision point to determine a result (*e.g.*, negative, positive, adulterated, invalid, or substituted) or the need for further testing.

Designated employer representative (DER). An employee authorized by the employer to take immediate action(s) to remove employees from safety-sensitive duties, or cause employees to be removed from these covered duties, and to make required decisions in the testing and evaluation processes. The DER also receives test results and other communications for the employer, consistent with the requirements of this part. Service agents cannot act as DERs.

Dilute specimen. A urine specimen with creatinine and specific gravity values that are lower than expected for human urine.

DOT, The Department, DOT Agency. These terms encompass all DOT agencies, including, but not limited to, the Federal Aviation Administration (FAA), the Federal Railroad Administration (FRA), the Federal Motor Carrier Safety Administration (FMCSA), the Federal Transit Administration (FTA), the National Highway Traffic Safety Administration (NHTSA), the Pipeline and Hazardous Materials Safety Administration (PHMSA), and the Office of the Secretary (OST). For purposes of this part, the United States Coast Guard (USCG), in the Department of Homeland Security, is considered to be a DOT agency for drug testing purposes only since the USCG regulation does not incorporate Part 40 for its alcohol testing program. These terms include any designee of a DOT agency.

Drugs. The drugs for which tests are required under this part and DOT agency regulations are marijuana, cocaine, amphetamines, phencyclidine (PCP), and opioids.

Employee. Any person who is designated in a DOT agency regulation as subject to drug testing and/or alcohol testing. The term includes individuals

currently performing safety-sensitive functions designated in DOT agency regulations and applicants for employment subject to pre-employment testing. For purposes of drug testing under this part, the term employee has the same meaning as the term “donor” as found on CCF and related guidance materials produced by the Department of Health and Human Services.

Employer. A person or entity employing one or more employees (including an individual who is self-employed) subject to DOT agency regulations requiring compliance with this part. The term includes an employer’s officers, representatives, and management personnel. Service agents are not employers for the purposes of this part.

Error Correction Training. Training provided to BATs, collectors, and screening test technicians (STTs) following an error that resulted in the cancellation of a drug or alcohol test. Error correction training must be provided in person or by a means that provides real-time observation and interaction between the instructor and trainee.

Evidential Breath Testing Device (EBT). A device that is approved by the National Highway Traffic Safety Administration (NHTSA) for the evidential testing of breath at the .02 and .04 alcohol concentrations, and appears on ODAPC’s Web page for “Approved Evidential Breath Measurement Devices” because it conforms with the model specifications available from NHTSA.

HHS. The Department of Health and Human Services or any designee of the Secretary, Department of Health and Human Services.

Initial drug test. The first test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

Initial specimen validity test. The first test used to determine if a specimen is adulterated, diluted, substituted, or invalid.

Invalid result. The result reported by an HHS-certified in accordance with the criteria established by HHS when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

Laboratory. Any U.S. laboratory certified by HHS under the National Laboratory Certification Program as meeting the minimum standards set by HHS; or, in the case of foreign laboratories, a laboratory approved for participation by DOT under this part.

Limit of Detection (LOD). The lowest concentration at which the analyte (*e.g.*, drug or drug metabolite) can be identified.

Limit of Quantitation (LOQ). For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.*, drug or drug metabolite) can be accurately established.

Medical Review Officer (MRO). A person who is a licensed physician and who is responsible for receiving and reviewing laboratory results generated by an employer's drug testing program and evaluating medical explanations for certain drug test results.

Negative result. The result reported by an HHS-certified laboratory to an MRO when a specimen contains no drug or the concentration of the drug is less than the cutoff concentration for the drug or drug class and the specimen is a valid specimen.

Non-negative specimen. A specimen that is reported as adulterated, substituted, positive (for drug(s) or drug metabolite(s)), or invalid.

Office of Drug and Alcohol Policy and Compliance (ODAPC). The office in the Office of the Secretary, DOT, that is responsible for coordinating drug and alcohol testing program matters within the Department and providing information concerning the implementation of this part.

Oral fluid specimen. A specimen that is collected from an employee's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands. An oral fluid specimen is considered to be a direct observation collection for all purposes of this part.

Oxidizing adulterant. A substance that acts alone or in combination with other substances to oxidize drugs or drug metabolites to prevent the detection of the drug or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

Primary specimen. In drug testing, the specimen bottle that is opened and tested by a first laboratory to determine whether the employee has a drug or drug metabolite in his or her system; and for the purpose of specimen validity testing. The primary specimen is the portion of the donor's subdivided specimen designated as the primary ("A") specimen by the collector to distinguish it from the split ("B") specimen, as defined in this section.

Positive result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the cutoff concentrations.

Qualification Training. The training required in order for a collector, BAT, MRO, SAP, or STT to be qualified to perform their functions in the DOT drug and alcohol testing program. Qualification training may be provided by any appropriate means (*e.g.*, classroom instruction, internet application, CD-ROM, video).

Reconfirmed. The result reported for a split (Bottle B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (Bottle A) specimen.

Refresher Training. The training required periodically for qualified collectors, BATs, and STTs to review basic requirements and provide instruction concerning changes in technology (*e.g.*, new testing methods that may be authorized) and amendments, interpretations, guidance, and issues concerning this part and DOT agency drug and alcohol testing regulations. Refresher training can be provided by any appropriate means (*e.g.*, classroom instruction, internet application, CD-ROM, video).

Rejected for testing. The result reported by an HHS-certified laboratory when no tests are performed for a specimen because of a fatal flaw or a correctable flaw that is not corrected.

Screening Test Technician (STT). A person who instructs and assists employees in the alcohol testing process and operates an ASD.

Secretary. The Secretary of Transportation or the Secretary's designee.

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Service agent. Any person or entity, other than an employee of the employer, who provides services to employers and/or employees in connection with DOT drug and alcohol testing requirements. This includes, but is not limited to, collectors, BATs and STTs, laboratories, MROs, substance abuse professionals, and C/TPAs. To act as service agents, persons and organizations must meet DOT qualifications, if applicable. Service agents are not employers for purposes of this part.

Shipping container. A container that is used for transporting and protecting specimen bottles and associated documents from the collection site to the laboratory.

Specimen. Fluid, breath, or other material collected from an employee at the collection site for the purpose of a drug or alcohol test.

Specimen bottle. The bottle that, after being sealed and labeled according to the procedures in this part, is used to hold a primary (“A”) or split (“B”) specimen during transportation to the laboratory. In the context of oral fluid testing, it may be referred to as a “vial,” “tube,” or “bottle.”

Split specimen. In drug testing, the specimen that is sent to a first laboratory and stored with its original seal intact, and which is transported to a second laboratory for retesting at the employee’s request following MRO verification of the primary specimen as positive, adulterated or substituted.

Split specimen collection. A collection in which the single specimen collected is divided into two separate specimen bottles, the primary specimen (Bottle A) and the split specimen (Bottle B).

SSN or Employee ID No. This number serves as a unique identifier that must be used on the Federal Drug Testing Custody and Control Form (CCF) or Alcohol Testing Form (ATF) for a donor, on the MRO’s reports, on SAP reports, or on other documents that are required under this part. For all purposes of this part, this term means: only the Commercial Driver’s License (CDL) Number and State of issuance for drivers tested under the authority of the Federal Motor Carrier Safety Administration (FMCSA); and, for all drivers and other safety-sensitive employees tested under the authority of the other

DOT agencies, this can be the individual’s actual Social Security Number, a unique identifier issued by the employer, a State-issued identification card number, a State-issued driver’s license number (including a CDL number) or any other State-issued or federally-issued identification number.

Stand-down. The practice of temporarily removing an employee from the performance of safety-sensitive functions based only on a report from a laboratory to the MRO of a confirmed positive test for a drug or drug metabolite, an adulterated test, or a substituted test, before the MRO has completed verification of the test result.

Substance Abuse Professional (SAP). A person who evaluates employees who have violated a DOT drug and alcohol regulation and makes recommendations concerning education, treatment, follow-up testing, and aftercare.

Substituted specimen. An employee’s specimen not consistent with a normal human specimen, as determined by HHS (e.g., a urine specimen, with creatinine and specific gravity values that are so diminished, or so divergent that they are not consistent with normal human urine).

Undiluted (neat) oral fluid. An oral fluid specimen to which no other solid or liquid has been added. For example: A collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.

Urine specimen. Urine collected from an employee at the collection site for the purpose of a drug test.

Verified test. A drug test result or validity testing result from an HHS-certified laboratory that has undergone review and final determination by the MRO.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001; 71 FR 49384, Aug. 23, 2006; 71 FR 55347, Sept. 22, 2006; 73 FR 35969, June 25, 2008; 75 FR 49861, Aug. 16, 2010; 76 FR 59577, Sept. 27, 2011; 80 FR 19553, Apr. 13, 2015; 81 FR 52365, Aug. 8, 2016; 82 FR 52243, Nov. 13, 2017; 88 FR 27636, May 2, 2023]