Handout # 3

HHS Mandatory Guidelines for Federal Drug Testing Programs (published 11/25/08) Revisions that NRC Does Not Intend to Implement in Part 26 Rulemaking

HHS Guidelines Section Number	Description of HHS Guidelines Revision
1.1	Revised to apply to collectors and MROs.
1.5	Revised the definitions of the terms: “cutoff,” “dilute specimen,” “failed to reconfirm,” “initial validity test,” “negative result,” “performance testing (PT) sample,” “quality control (QC) sample,” “reconfirmed.” Revised the names of the terms: “adulterated,” “confirmatory validity test,” “validity test,” “initial validity test,” “split specimen,” “substituted.” Added the terms: “alternate response person,” “alternate responsible technician,” “limit of detection,” “limit of quantitation,” “specimen.” Removed the terms: “follow-up test,” “non-negative,” “post-accident test,” “pre-employment test,” “random test,” “reasonable suspicion/cause test,” “return to duty test.”
2.2	Added a description of the circumstances under which a Federal agency may collect a specimen, including requirements for pre-employment and return-to-duty testing.
3.1	Revised to clarify that all specimens, not only those collected from Federal agency applicants or at random, will be tested for the same drugs and specimen validity tests.
3.2(a)	Added clarification regarding cases where Federal agencies opt to test for a drug for which an immunoassay test is not available.
3.2(a)	Added that the donor may request that Bottle B be tested at another HHS-certified laboratory by the confirmatory method.
3.3	Deleted phrase "unless otherwise authorized by law" to clarify that Federal Agency specimens must only be tested for drugs and to determine their validity.
3.4	Combined tables presenting initial and confirmatory cutoff concentrations.
4.5	Added training requirements for collectors that train other collectors.
4.6	Added requirement that Federal agency must ensure that collector training requirements are met.
5.1	Added allowance for a collection site to be a permanent or temporary facility. Also allows for a public restroom to be a collection site in urgent situations.
7.2	Added requirement that the collection items used must not affect the specimen collection.
8.2	Added requirement for collection area to have no source of water that is not secured during collection. If there is a sink or toilet that cannot be secured the collection must be monitored for sounds that suggest tampering.
8.3(f)	Added to direct the collector to allow the donor to read a form summarizing the collection process.
8.4	Added more detail regarding the steps in the collection process.
8.5	Revised to address cases involving "shy bladder." If donor cannot provide a specimen on initial attempt, he or she may (not required to) drink fluids and take up to 3 hours to provide a specimen.
8.6(e)(1) and (2)	Revised to require 45mL and requires the collector to discard anything less that 45mL and re-collect.
8.8	Revised to require concurrence from supervisor that direct observation is necessary. Added the actions the collector must take when a donor refuses direct observation.

HHS Guidelines Section Number	Description of HHS Guidelines Revision
8.13	Revised collection site inspection requirements to require agencies to inspect 5% of collection sites or a maximum of 50 sites per year. Additionally, agencies must investigate reported collection site deficiencies.
9.3(b)(2)	Revised pH specifications to challenge the pH tests used by IITFs.
Subpart K	Removed requirement that certified laboratory must inform its private sector clients when it uses testing procedures different from those used for Federal agency specimens.
11.4	Revised to require a laboratory to have multiple responsible persons (RPs) or one RP and an alternate RP.
11.4(c)	Revised to require that the alternate RP must be found acceptable during an on-site inspection of the laboratory.
11.5(a)(1)	Revised to allow a certifying scientist to have at least a bachelor's degree "or equivalent."
11.6	Revised to require that training for other laboratory personnel must be documented.
11.7	Revised to require the authorized escort to enter his or her name in the record used to document the entry of authorized visitors.
11.9	Revised to require HHS-certified laboratory to test each specimen received from an HHS-certified IITF in the same manner as if it had not been previously tested.
11.10	Clarified that drug test kits must be approved, cleared or otherwise recognized by FDA as accurate and reliable.
11.10(d)	Revised to allow a second initial drug test if the second test has a different specificity than the first initial drug test.
11.19(g)	Added to require laboratory to contact MRO prior to reporting specimens meeting "invalid result" criteria.
11.20(c)	Revised to require a Federal agency to specify a period of time when requesting a laboratory to retain a specimen beyond one year. Deleted requirement to maintain specimen under legal challenge for an indefinite period.
11.21	Revised to specify the records that the HHS-certified laboratory must maintain when there is a legal challenge to a test result. Revised to allow the Federal agency to request a laboratory to maintain a copy of the documentation for a specified period of time. Revised to allow HHS-certified laboratories to maintain documentation package records for more than the normal 2 years.
11.22(d)	Revised to require an HHS-certified laboratory to make only one qualified individual available to testify.
11.23	Revised to require the curriculum vitae for the responsible person be available to Federal employees.
11.24	Revised to clarify the relationship between the MRO and the HHS Laboratory.
13.3(d)	Revised to address requirement that MRO medically evaluate donors who were unable to provide a sufficient amount of urine.
13.4	Deleted guidance regarding MRO actions in response to a second specimen collected after an invalid result for which there is no valid medical explanation.
13.5 and 13.6	Added to describe MRO actions when a collector reports that a donor was unable to provide a urine specimen.
13.9	Deleted references to point of collection testing (POCT).