Nuclear Regulatory Commission

§ 26.153

individual when that proceeding is
based on urinalysis results reported by
the licensee testing facility.

d) The licensee testing facility shall
prepare the information required for
the annual report to the NRC, as re-
quired in § 26.717.

e) The data in the annual report to
the NRC must be presented for either
the cutoff levels specified in this part,
or for more stringent cutoff levels, if
the FFD program uses more stringent
cutoff levels for drugs and drug me-
tabolites. If the FFD program tests for
drugs and drug metabolites that are
not specified in §26.31(d)(1), the sum-
mary must also include the number of
positive test results and the cutoff lev-
eels used for those drugs and drug me-
tabolites.

(f) The designated FFD program offi-
cial shall use the available information
from the licensee testing facility’s va-

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§ 26.151 Purpose.

This subpart contains requirements
for the HHS-certified laboratories that
licensees and other entities who are
subject to this part use for testing
urine specimens for validity and the
presence of drugs and drug metabolites.

§ 26.153 Using certified laboratories
for testing urine specimens.

(a) Licensees and other entities who
are subject to this part shall use only
laboratories certified under the Depart-
ment of Health and Human Services
(HHS) Mandatory Guidelines for Fed-
eral Workplace Drug Testing Programs
[published in the FEDERAL REGISTER on
April 11, 1988 (53 FR 11970), and as
amended, June 9, 1994 (59 FR 29908), No-
vember 13,1998 (63 FR 63463), and April
13, 2004 (69 FR 19643) for specimen va-
dility and drug testing, except as per-
mitted under §26.3l(d)(3)(ii). Informa-
tion concerning the current certifi-
cation status of laboratories is avail-
able from the Division of Workplace
Programs, Center for Substance Abuse
Prevention, Substance Abuse and Men-
tal Health Services Administration,
Room 815, 5600 Fishers Lane, Rockwall
2 Bldg., Rockville, Maryland 20857.

(b) HHS-certified laboratories shall
have the capability, at the same prem-
ises, to perform both initial and con-
firmatory tests for specimen validity
and for each drug and drug metabolite
for which the HHS-certified laboratory
provides services to the licensee or
other entity.

(c) An HHS-certified laboratory may
not subcontract and shall perform all
work with its own personnel and equip-
ment unless otherwise authorized by
the licensee or other entity.

(d) Licensees and other entities shall
use only HHS-certified laboratories
that agree to follow the same rigorous
specimen testing, quality control, and
chain-of-custody procedures when test-
ing for more stringent cutoff levels as
may be specified by licensees and other
entities for the classes of drugs identi-

(e) Before awarding a contract to an
HHS-certified laboratory, the licensee
or other entity shall ensure that quali-
ﬁed personnel conduct a pre-award in-
spection and evaluation of the proce-
dural aspects of the laboratory’s drug
testing operations. However, if an
HHS-certified laboratory loses its cer-
tiﬁcation, in whole or in part, a li-
censee or other entity may imme-
diately begin using another HHS-cer-
tiﬁed laboratory that is being used by
another licensee or entity who is sub-
ject to this part, as permitted by
§26.41(g)(5).

(f) All contracts between licensees or
other entities who are subject to this

Subpart G—Laboratories Certified
by the Department of Health
and Human Services

§ 26.151 Purpose.

This subpart contains requirements
for the HHS-certified laboratories that
licensees and other entities who are
subject to this part use for testing
urine specimens for validity and the
presence of drugs and drug metabolites.

§ 26.153 Using certified laboratories
for testing urine specimens.

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laboratories certified under the Depart-
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tion concerning the current certifi-
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able from the Division of Workplace
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tal Health Services Administration,
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(b) HHS-certified laboratories shall
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firmatory tests for specimen validity
and for each drug and drug metabolite
for which the HHS-certified laboratory
provides services to the licensee or
other entity.

(c) An HHS-certified laboratory may
not subcontract and shall perform all
work with its own personnel and equip-
ment unless otherwise authorized by
the licensee or other entity.

(d) Licensees and other entities shall
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that agree to follow the same rigorous
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diately begin using another HHS-cer-
tiﬁed laboratory that is being used by
another licensee or entity who is sub-
ject to this part, as permitted by
§26.41(g)(5).

(f) All contracts between licensees or
other entities who are subject to this
part and HHS-certified laboratories must require the laboratory to implement all applicable requirements of this part. At a minimum, licensees’ and other entities’ contracts with HHS-certified laboratories must include the following requirements:

(1) Laboratory facilities shall comply with the applicable provisions of any State licensor requirements;

(2) The laboratory shall make available qualified personnel to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on urinalysis results reported by the HHS-certified laboratory;

(3) The laboratory shall maintain test records in confidence, consistent with the requirements of §26.37, and use them with the highest regard for individual privacy.

(4) Consistent with the principles established in section 503 of Public Law 100–71, any employee of a licensee or other entity who is the subject of a drug test (or his or her representative designated under §26.37(d)) shall, on written request, have access to the laboratory’s records related to his or her validity and drug test and any records related to the results of any relevant certification, review, or revocation-of-certification proceedings;

(5) The laboratory may not enter into any relationship with the licensee’s or other entity’s MRO(s) that may be construed as a potential conflict of interest, including, but not limited to, the relationships described in §26.183(b), and may not derive any financial benefit by having a licensee or other entity use a specific MRO; and

(6) The laboratory shall permit representatives of the NRC and any licensee or other entity using the laboratory’s services to inspect the laboratory at any time, including unannounced inspections.

(g) If licensees or other entities use a form other than the current Federal custody-and-control form, licensees and other entities shall provide a memorandum to the laboratory explaining why a non-Federal form was used, but must ensure, at a minimum, that the form used contains all the required information on the Federal custody-and-control form.


§ 26.155 Laboratory personnel.

(a) Day-to-day management of the HHS-certified laboratory. HHS-certified laboratories shall have a responsible person to assume professional, organizational, educational, and administrative responsibility for the laboratory’s drug testing facilities.

(1) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are as follows:

(i) Certification by the appropriate State as a laboratory director in forensic or clinical laboratory toxicology; or

(ii) A PhD in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in paragraphs (a)(1)(i) through (a)(1)(iii) of this section, the responsible person shall also have the following minimum qualifications:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse; and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology (e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors that qualify the individual as an expert witness in forensic toxicology).

(2) This individual shall be engaged in and responsible for the day-to-day management of the testing laboratory, even if another individual has overall responsibility for an entire multi-specialty laboratory.

(3) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and