## Subpart F: Licensee Testing Facilities

### 26.121 Purpose

This section of the final rule imposes no incremental cost and affords no saving because it merely states that Subpart F contains requirements for laboratories operated by licensees to perform initial drug testing and validity testing on urine specimens.

### 26.123 Testing facility capabilities

This section of the final rule revises former requirements in Section 2.7(l)(2) in Appendix A to Part 26, which required that licensee testing facilities must have the capability to perform initial drug tests on urine specimens for each of the five drugs and drug metabolites as required in § 2.7(e)(1). The final rule adds a requirement that each licensee testing facility must have the capability to perform validity screening or initial validity tests on urine specimens. This analysis captures any incremental costs associated with this section in § 26.131 of the final rule.

### 26.125 Licensee testing facility personnel

This section of the final rule [including paragraphs (a)–(c)] imposes no incremental cost and affords no saving because it restates and clarifies former requirements in Section 2.6(a)–(c) in Appendix A to Part 26, which pertained to the requirements for licensee testing facility personnel responsible for the day-to-day management of operations and supervision of testing technicians, other technicians, non-technical staff, and licensee testing facility personnel files. Paragraph 26.125(b) of the final rule revises former requirement in Section 2.6(c), which described collector proficiency requirements, by adding a new requirement that technicians who perform urine specimen testing have documented proficiency in operating the testing instruments and devices used at the testing facility. This new provision will result in no incremental cost or saving because it is consistent with existing licensee testing facility training practices and documentation procedures.

### 26.127 Procedures

This section of the final rule clarifies former requirements in Sections 2.2 and 2.7 in Appendix A to Part 26 as discussed in paragraphs (a)–(f) below. No incremental costs or savings will result directly from the clarifications in this final section. However, FFD programs with onsite licensee testing facilities will incur incremental costs to comply with the requirements in this section and therefore must revise current laboratory policies and procedures to incorporate necessary changes related to other sections of Subpart F (e.g., validity testing, modified cutoff levels for marijuana and opiates, blind performance specimen testing, quality assurance procedures). The analysis evaluates the incremental costs of all licensee testing facility policy revisions required because of the final rule revisions in this section of the analysis.

*The one-time cost per FFD program with onsite licensee testing facilities* is estimated as follows:

$(HOURS_{FFD\ manager} \times WAGE_{FFD\ manager}) + (HOURS_{Lab\ supervisor} \times WAGE_{Lab\ supervisor}) + (HOURS_{Clerical} \times WAGE_{Clerical}) + (HOURS_{Legal} \times WAGE_{Legal})$

| Parameter | Description |
|---|---|
| $HOURS_{FFD\ manager}$ | Hours of FFD manager's time to revise the laboratory procedures manual (as discussed in the assumptions below) |
| $WAGE_{FFD\ manager}$ | FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11) |
| $HOURS_{Lab\ supervisor}$ | Hours of laboratory supervisor's time to revise the laboratory procedures manual (as discussed in the assumptions below) |
| $WAGE_{Lab\ supervisor}$ | Laboratory supervisor wage rate (as discussed in Appendix 2, Exhibit A2-11) |
| $HOURS_{Clerical}$ | Hours of clerical personnel time to revise the laboratory procedures manual (as discussed in the assumptions below) |
| $WAGE_{Clerical}$ | Clerical personnel wage rate (as discussed in Appendix 2, Exhibit A2-11) |
| $HOURS_{Legal}$ | Hours of legal time to review the laboratory procedures manual (as discussed in the assumptions below) |
| $WAGE_{Legal}$ | Legal wage rate (as discussed in Appendix 2, Exhibit A2-11) |

*Assumptions:*

- Hours for procedure revisions per FFD program with onsite licensee testing facilities by labor category (total of 360 hours):
  - FFD manager: 120 hours.
  - Laboratory supervisor: 160 hours.
  - Clerical: 40 hours.
  - Legal: 40 hours.

- Each FFD program with onsite licensee testing facilities uses a single procedures manual for all testing facilities.

**Paragraph 26.127(a)**

The paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements within Section 2.2 in Appendix A to Part 26, which related to the maintenance and documentation of procedures for the collection, shipment, and accession of urine specimens.

**Paragraph 26.127(b)**

The paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change the former requirements in Section 2.7(a)(2) in Appendix A to Part 26, which pertained to the content and implementation of specimen chain-of-custody procedures for licensee testing facilities.

**Paragraph 26.127(c)**

The paragraph of the final rule revises without substantive change former requirements within Section 2.7(o)(1) in Appendix A to Part 26 which specified that licensee testing facilities must maintain a procedures manual detailing the numerous components of the drug testing process. The final paragraph extends the former requirement to include a provision requiring documentation of standard operating procedures for each specimen validity testing assay performed. In addition, this final paragraph requires that the licensee testing facility maintain written procedures, but no longer specifies that these procedures must be maintained in a "procedure manual." Incremental costs associated with revisions to the licensee testing facility policy and procedures are discussed in connect with § 26.127.

**Paragraph 26.127(d)**

The paragraph of the final rule imposes no incremental cost and affords no saving because it restates a former requirement in Section 2.7(o)(3)(iii) in Appendix A to Part 26.

**Paragraph 26.127(e)**

The paragraph of the final rule imposes no incremental cost and affords no saving because it restates and clarifies former requirements in Section 2.7(o)(4) in Appendix A to Part 26, which maintained that a licensee testing facility must develop, implement, and maintain procedures for remedial actions if systems are out of acceptable limits or errors are detected. This paragraph adds a new requirement for licensee testing facilities that use validity screening testing tests to maintain procedures for instrumented and non-instrumented testing. As discussed in § 26.131(a) of the analysis, the analysis assumes that no licensee testing facilities will conduct validity screening tests. Therefore, this revised provision will result in no incremental cost or saving because license testing facilities will not have to maintain procedures for instrumented and non-instrumented validity screening tests.

**26.129 Assuring specimen security, chain of custody, and preservation**

**Paragraph 26.129(a)**

There are no incremental costs or savings from this paragraph because it clarifies former requirements in Section 2.7(a)(1) in Appendix A to Part 26.

**Paragraph 26.129(b)**

This paragraph of the final rule revises former requirements in Section 2.7(b)(1) in Appendix A to Part 26, which required that licensee testing facility personnel must inspect each package containing urine specimens to identify any evidence of possible tampering and must notify licensee officials of any tampering as soon as possible, but within 8 hours of identifying a potential tampering incident. By contrast, the provisions in this paragraph will require each licensee testing facility to conduct an investigation into possible tampering and take corrective actions when necessary. This paragraph of the final rule adds a provision to require the licensee

testing facility to obtain a memorandum for the record from the specimen collector to document correction of the discrepancy, which must accompany the specimen(s) and custody-and-control forms to the HHS-certified laboratory, if the specimen(s) must be transferred. This paragraph also adds specific instances that would require testing of a specimen to be cancelled. If the licensee testing facility personnel identify any reason to believe that the integrity and/or identity of a specimen is in question, the specimen is not to be tested and the licensee or other entity must ensure that another collection occurs as soon as reasonably practicable. This analysis estimates that no incremental costs or savings will result from this final paragraph because the requirements are believed to be consistent with existing licensee practices used to address issues associated with discrepancies of information, specimen bottles, and/or the specimen custody-and-control form. The new requirement that a memorandum for the record be obtained from the specimen collector only ensures that the error correction is made to the custody-and-control form, but the level of effort to resolve the error is unchanged.

**Paragraph 26.129(c)**

This paragraph of the final rule clarifies and revises former requirements in Section 2.7(b)(2) in Appendix A to Part 26, which pertained to the handling of urine specimens at licensee testing facilities and the use of chain-of-custody forms. Specifically, this paragraph clarifies that licensee testing facilities must use laboratory chain-of-custody forms or other appropriate methods of tracking aliquot custody and control while conducting validity testing (screening and/or initial) and initial drug testing on urine specimens. This final paragraph also establishes that both the original specimen and the original specimen custody-and-control form must remain in secure storage. Finally, this paragraph clarifies that licensee testing facilities may discard specimens as soon as practical after receiving negative results for validity screening and/or initial validity and initial drug tests. No incremental costs or savings will result from this final paragraph because it is considered to be consistent with existing licensee testing facility practices for urine specimen handling, storage, and disposal. The analysis does not quantify the costs for any licensee testing facilities to use alternative custody and control tracking methods to accommodate validity testing, as these costs, if any, are deemed to be insignificant.

**Paragraph 26.129(d)**

This final paragraph imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.7(a)(2) in Appendix A to Part 26, which pertained to chain-of-custody procedures and information required to be included on custody-and-control forms used to track urine specimens at licensee testing.

**Paragraph 26.129(e)**

This paragraph of the final rule clarifies and revises former requirements in Section 2.7(d) in Appendix A to Part 26, which pertained to the shipment of “presumptive positive” urine specimens to an HHS-certified laboratory for confirmatory testing. The former requirements did not designate a time by which the licensee testing facility must send a specimen identified as positive or of questionable validity to an HHS-certified laboratory. The final paragraph replaces

the term “presumptive positive” with “positive or of questionable validity” to account for drug positive specimens and specimens with validity test results that require additional testing and directs licensee testing facilities to send these specimens to an HHS-certified laboratory as soon as reasonably practical. No incremental costs or savings are estimated because the revised provision is consistent with current specimen shipping practices used by licensee testing facilities.

**Paragraph 26.129(f)**

This paragraph of the final rule clarifies and revises former requirements (which primarily appear in Section 2.7(c) in Appendix A to Part 26), as they relate to refrigerating specimens to protect them from degradation. This final paragraph restates portions of the former rule and adds a performance standard regarding “appropriate and prudent actions” to minimize specimen degradation. (Licensees would likely meet the performance standard by implementing the more specific criteria from the former rule, which are also restated in the final rule.) The revised paragraph also relaxes the refrigeration criteria for most specimens, but tightens them for specimens identified as positive or of questionable validity that will undergo validity screening, initial validity, or initial drug testing. The analysis assumes that the provisions are consistent with current industry practice. To the extent (if any) that the refrigeration standards (some relaxed, some tightened) might require licensees to change their operating practices, the net effect is likely to be negligible. As a result of these uncertainties (including a lack of data) and the likelihood that any impact would be negligible, this analysis does not quantify costs or savings resulting from this final paragraph.

**Paragraph 26.129(g)**

This paragraph of the final rule clarifies former requirements in Section 2.4(i) in Appendix A to Part 26, which specified packaging and shipping requirements for urine specimens that are sent from a licensee testing facility to an HHS-certified laboratory. No incremental costs or savings will result from this final paragraph because it is consistent with former requirements.

**Paragraph 26.129(h)**

This paragraph of the final rule clarifies that because couriers, express carriers, and postal service personnel do not have access to the custody-and-control forms or the specimen bottles, they are not required to document chain-of-custody of a urine specimen in transit. However, this paragraph adds a new requirement that the custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service. No incremental costs or savings will result from the final paragraph because it describes former courier, express carrier, and postal service shipment tracking practices.

**26.131 Cutoff levels for validity screening and initial validity tests**

**Paragraph 26.131(a)**

This paragraph of the final rule establishes that licensee testing facilities must conduct validity screening and/or initial validity testing on all urine specimens collected under the requirements in 10 CFR Part 26. Specimens with a validity screening and/or initial validity test result of questionable validity must be sent to an HHS-certified laboratory for further validity testing. The analysis assumes that all licensee testing facilities will choose to conduct initial validity testing (rather than validity screening testing) on all urine specimens. As discussed in the Statement of Considerations, NRC is allowing the use of validity screening tests for the potential future benefit of licensees and other entities even though no such devices currently meet the quality assurance and quality control requirements in § 26.137(b) of the final rule. All validity testing costs are considered incremental because this is a new regulatory requirement.[1] The analysis estimates all specimen validity testing costs in the discussion of § 26.131(b) of the final rule.

**Paragraph 26.131(b)**

This paragraph of the final rule establishes specimen validity testing requirements for licensee testing facilities and requires that each urine specimen be analyzed for creatinine, pH, and one or more oxidizing adulterants and specifies the cutoff levels for each validity test (screening and initial validity). The provisions in this paragraph prohibit licensees and other entities from using more stringent cutoff levels for validity tests than those specified in 10 CFR Part 26.

The regulatory analysis calculates under this paragraph not only the costs related to conducting initial validity testing at licensee testing facilities, but also the subsequent costs for some specimens to receive initial and confirmatory validity and drug testing at an HHS-certified laboratory, and the associated costs resulting from confirmed adulterated or substituted validity and/or positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen). Even though many of these costs are directly related to other provisions in the final rule, as referenced below, this approach consolidates the series of actions that are initiated under § 26.131, allowing for a unified (hence clearer) presentation of related actions and a simpler analysis.

One-time costs captured below consist of training laboratory technicians at licensee testing facilities in the methods and procedures to conduct initial validity testing, and the annual costs associated with conducting initial validity testing at licensee testing facilities on all urine specimens (including calibrating validity testing equipment), conducting initial and confirmatory validity testing at an HHS-certified laboratory for specimens with test results of questionable validity[2] from the licensee testing facility, the labor costs of MRO and FFD personnel for

[1]By assuming that no licensees currently conduct validity testing, the analysis overstates the incremental costs to be incurred by FFD programs as a result of the validity testing provisions. This assumption is necessary, however, because of the lack of available data regarding the types of validity testing being conducted throughout the industry.

[2] The final rule in § 26.5 created a definition for licensee testing facility validity test results. Any specimen that indicates the specimen may be adulterated, substituted, dilute, or invalid is referred to as having a validity test result of "questionable validity." The use of the term "questionable validity" is necessary because licensee testing facilities cannot conduct specific gravity testing to determine if a specimen is dilute or adulterated and therefore,

administrative activities for confirmed positive drug test results and/or confirmed adulterated or substituted validity test results, the costs of retesting some specimens with confirmed drug positive, adulterated, substituted, or invalid test results at the donor's request (MRO's request for invalid specimens), and the costs of the appeals process for some drug positive, adulterated, or substituted test results that donors choose to contest. In addition, because HHS certified laboratory testing procedures and required licensee actions vary based on the type of confirmatory validity test result (e.g., dilute, invalid), the analysis discusses the costs for each validity test result type separately (designated below as "Results A, B, and C").

- "Result A": adulterated and substituted specimens
- "Result B": dilute specimens
- "Result C": invalid specimens

*Annual cost per FFD program with an onsite licensee testing facility* is estimated as the *sum* of the following:

- Cost to conduct initial validity testing at onsite licensee testing facilities for all urine specimens

  $NUM_{validity} \times [COST_{validity\ test\ reagents} + (HOURS_{lab\ tech} \times WAGE_{lab\ tech})] \times NUM_{reactors}$

- Cost to conduct daily calibration of validity testing equipment

  $NUM_{days} \times [COST_{calibration\ reagents} + (HOURS_{lab\ tech\text{-}calibrate} \times WAGE_{lab\ tech})] \times NUM_{facilities}$

- Annualized cost of purchasing validity testing equipment (i.e., pH meter)[3]

  $NUM_{pH\ meter} \times COST_{pH\ meter} \times NUM_{facilities}$

- Cost of sending and testing all urine specimens with initial validity test result of questionable validity to an HHS-certified laboratory for initial and confirmatory validity testing (and drug testing under specific instances), as described by the following validity test result cases (Results A, B, and C).

  - Result A: HHS-certified laboratory validity testing costs for specimens with test results of adulterated or substituted consist of the following:

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NRC has decided to improve the clarity of the final rule by creating a single term to cover all specimens with a validity test result requiring further testing at an HHS-certified laboratory.

[3]The analysis assumes that each licensee testing facility will only need to purchase one pH meter to comply with the validity testing requirements because all licensee testing facilities already either lease or have purchased desktop sized drug testing instrument using enzyme immunoassay (EIA) technology to comply with the former requirements in 10 CFR Part 26. Reagents are commercially available for testing of creatinine and some adulterants using EIA based testing equipment. Creatinine and adulterant testing is performed on urine specimens using the same basic testing procedures as employed in conducting testing for each of the five drugs.

$$NUM_{validity} \times (PER_{adulterated} + PER_{substituted}) \times COST_{HHS\ validity\ testing} \times NUM_{reactors}$$

- Result B: HHS-certified laboratory validity testing costs for specimens with test results of dilute. Additional costs include confirmatory drug testing to the limit of detection (LOD) for some specimens.[4] The costs include the following:

$$NUM_{validity} \times PER_{dilute} \times (COST_{HHS\ validity\ testing} + COST_{HHS\ LOD\ testing}) \times NUM_{reactors}$$

- Result C: HHS-certified laboratory validity testing costs for specimens with a test results of invalid. Additional costs include collecting a second urine specimen under direct observation, as specified in § 26.185(f)(3) of the final rule, and then validity and drug testing the second specimen at an HHS-certified laboratory. The costs include the following:

$$NUM_{validity} \times PER_{invalid} \times [COST_{HHS\ validity\ testing} + (COST_{2nd\ collection} + COST_{HHS\ validity\ \&\ drug\ testing})] \times NUM_{reactors}$$

- Cost of subsequent actions for all adulterated, substituted, dilute, or invalid validity test results and positive drug test results identified because of the validity testing requirements in § 26.131(b) and § 26.185(f)(3) (sum of adulterated, substituted, dilute, and invalid validity test results and positive drug tests from Results A, B, and C). FFD programs with onsite licensee testing facilities may also incur costs associated with some donors requesting the retesting of an aliquot of a single specimen or the testing of their split specimen and/or some donors appealing confirmed adulterated or substituted validity and/or positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen)

  - Cost for actions subsequent to confirmed adulterated or substituted validity, and/or positive drug (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen) test results

$$NUM_{validity} \times [(PER_{adulterated} + PER_{substituted} + (PER_{dilute} \times PER_{positive\text{-}dilute}) + (PER_{invalid} \times PER_{drug\ positive\ 2nd\ collection}))] \times COST_{subsequent\ actions} \times NUM_{reactors}$$

  - When requested by some donors, the cost of retesting specimens with confirmed adulterated or substituted validity, and/or positive drug (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen) test results at a second HHS-certified laboratory

$$NUM_{validity} \times [(PER_{adulterated} + PER_{substituted} + (PER_{dilute} \times PER_{positive\ at\ LOD}) + (PER_{invalid} \times$$

[4]Paragraph 26.163(a)(2) of the final rule permits FFD programs to require confirmatory LOD drug testing for any drug with an initial drug test result equal to or greater than 50 percent of the cutoff calibrator.

$PER_{drug\ positive\ 2nd\ collection}))] \times PER_{retest} \times COST_{retest} \times NUM_{reactors}$

- When requested by some donors, the cost of the appeals process for confirmed adulterated or substituted validity and/or positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen)

$$NUM_{validity} \times [(PER_{adulterated} + PER_{substituted} + (PER_{dilute} \times PER_{positive\ at\ LOD}) + (PER_{invalid} \times PER_{drug\ positive\ 2nd\ collection}))] \times PER_{appeal} \times [(HOURS_{FFD\ manager} \times WAGE_{FFD\ manger}) + (HOURS_{Worker} \times WAGE_{Worker})] \times NUM_{reactors}$$

*One time cost per FFD program with onsite licensee testing facilities* is estimated as the following:

- One time cost to train laboratory technicians in the procedures and methods to conduct initial validity tests.[5]

$$[(NUM_{technicians} \times HOURS_{tech\ training} \times NUM_{training\ courses}) + COST_{training\ course}] \times NUM_{facilities}$$

| **Parameter** | **Description** |
|---|---|
| $NUM_{validity}$ | Number of validity tests per reactor per year (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12) |
| $COST_{validity\ test\ reagents}$ | Cost of reagents used to perform initial validity testing (pH, creatinine, and one adulterant) per urine specimen at an onsite licensee testing facility (as discussed in Appendix 2, Exhibit A2-13) |
| $HOURS_{lab\ tech}$ | Hours of time for a laboratory technician to conduct initial validity testing (pH, creatinine, and one adulterant) per urine specimen at an onsite licensee testing facility (as discussed in Appendix 2, Exhibit A2-13) |
| $WAGE_{lab\ tech}$ | Laboratory technician wage rate (as discussed in Appendix 2, Exhibit A2-11) |
| $NUM_{days}$ | Number of days that a licensee testing facility conducts drug and validity testing per year (as discussed in assumptions below) |
| $COST_{calibration\ reagents}$ | Cost of reagents used to perform daily calibration of validity testing equipment at a licensee testing facility (as discussed in Appendix 2, Exhibit A2-13) |
| $HOURS_{lab\ tech\ calibrate}$ | Hours of time per day for a laboratory technician at a licensee testing facility to conduct daily calibration of validity testing equipment (as discussed in Appendix 2, Exhibit A2-13) |
| $NUM_{pH\ meter}$ | Number of pH meters purchased per licensee testing facility per year. (as discussed in the assumptions below) |
| $COST_{pH\ meter}$ | Annualized cost per pH meter, which includes the cost of replacement probes (as discussed in the assumptions below and in Appendix 2, Exhibit A2-13) |
| $PER_{adulterated}$ | Percentage of urine specimens with validity test results of adulterated (as |

[5]Additional laboratory technician training will be necessary because of normal employee turnover at onsite licensee testing facilities. However, this analysis estimates no incremental cost because it is assumed that laboratory technicians will receive on-the-job training as part of their normal training activities.

| Parameter | Description |
|---|---|
| | discussed in Appendix 2, Exhibit A2-12) |
| $PER_{substituted}$ | Percentage of urine specimens with validity test results of substituted (less than 2 mg/dL of creatinine) (as discussed in Appendix 2, Exhibit A2-12) |
| $COST_{HHS\ validity\ testing}$ | Cost of conducting initial and confirmatory validity testing at an HHS-certified laboratory per urine specimen with an initial validity test result of questionable validity determined at an onsite licensee testing facility. Costs included preparation of urine specimen and shipping costs to the HHS-certified laboratory (as discussed in the assumptions below) |
| $PER_{dilute}$ | Percentage of urine specimens with validity test results of dilute (as discussed in Appendix 2, Exhibit A2-12) |
| $COST_{HHS\ LOD\ testing}$ | Cost per specimen to conduct initial drug testing and confirmatory drug testing to the level of detection (LOD) for drug(s) identified during initial testing, as permitted by § 26.163(a)(2) of the final rule (as discussed in Appendix 2, Exhibit A2-13) |
| $PER_{invalid}$ | Percentage of urine specimens with validity test results of invalid (as discussed in Appendix 2, Exhibit A2-12) |
| $COST_{2nd\ collection}$ | Cost of collecting a second urine specimen under direct observation from a donor with a confirmatory validity test result of invalid for the initial urine specimen collected. The cost of the second collection includes the labor for the donor's travel time to and from the collection site, donor's time spent at the collection site, as well as the labor of the collector (as discussed in Appendix 2, Exhibit A2-13) |
| $COST_{HHS\ validity\ \&\ drug\ testing}$ | Cost of validity and drug testing a urine specimen that is sent by an onsite licensee testing facility to an HHS-certified laboratory for testing. Costs include confirmatory drug and/or validity testing when necessary (as discussed in Appendix 2, Exhibit A2-13) |
| $PER_{positive\ at\ LOD}$ | Percentage of dilute specimens that test positive for drug(s) during initial testing (equal to or greater than 50 percent of the cutoff calibrator) and at confirmatory LOD testing (as discussed in the assumptions below) |
| $PER_{drug\ positive\ 2nd\ collection}$ | Percentage of specimens collected under direct observation as a result of an initial specimen with an invalid test result that is positive for drugs (as discussed in the assumptions below) |
| $COST_{subsequent\ actions}$ | Labor costs associated with MRO and FFD program personnel activities and administrative actions resulting from a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result (as discussed in Appendix 2, Exhibit A2-13) |
| $PER_{retest}$ | Percentage of urine specimens with confirmed positive drug, and/or adulterated, or substituted validity test results retested at the request of the donor at a second HHS-certified laboratory (as discussed in the assumptions below) |
| $COST_{retest}$ | Cost of specimen retesting at a second HHS-certified laboratory including specimen preparation and shipping costs (as discussed in Appendix 2, Exhibit A2-13) |
| $PER_{appeal}$ | Percentage of confirmed positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and |

| Parameter | Description |
|---|---|
| | positive test results following the second collection for a donor that produced an invalid specimen) and/or adulterated or substituted validity test results appealed by some donors (as discussed in the assumptions below) |
| $HOURS_{FFD\ manager}$ | Average amount of FFD manager time per appeal for a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result appealed by some donors (as discussed in the assumptions below) |
| $WAGE_{FFD\ manger}$ | FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11) |
| $HOURS_{Worker}$ | Average amount of worker time per appeal process for a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result (as discussed in the assumptions below) |
| $WAGE_{Worker}$ | Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11) |
| $NUM_{technicians}$ | Number of laboratory technicians per licensee testing facility (as discussed in the assumptions below) |
| $HOURS_{tech\ training}$ | Length of laboratory technician training course (as discussed in assumptions below) |
| $NUM_{training\ courses}$ | Number of laboratory technician training courses per licensee testing facility (as discussed in the assumptions below) |
| $COST_{training\ course}$ | Cost per laboratory technician training course conducted by a commercial vendor at the licensee testing facility (as discussed in the assumptions below) |
| $NUM_{facilities}$ | Number of licensee testing facilities per FFD program (as discussed in Appendix 2, Exhibit A2-14) |
| $NUM_{reactors}$ | Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14) |

*Assumptions:*

- Number of validity tests per reactor per year is equivalent to the number of drug tests conducted per year per reactor.

- Each licensee facility that conducts onsite testing has one testing facility.

- Each licensee testing facility purchases one pH meter, which is replaced every six years. Each pH meter requires a replacement probe every two years.

- Number of days a licensee testing facility operates per year: 365 days.

- Cost per specimen to conduct initial and confirmatory validity testing at an HHS-certified laboratory for a urine specimen with an adulterated, substituted, dilute, or invalid initial validity test result at an onsite licensee testing facility: $1.50 +

(cost of drug test at HHS-certified laboratory, as discussed in Appendix 2, Exhibit A2-13). FFD programs contract with HHS-certified laboratories at a fixed price per urine specimen analysis which includes drug testing (initial and confirmatory when necessary) and will also include specimen validity testing (initial and confirmatory when necessary) under the final rule. The analysis assumes that the testing cost per urine specimen will increase by $1.50 to account for validity testing in addition to drug testing costs. This testing event did not occur under the former rule because no validity testing was required (i.e., no specimen would be sent to an HHS laboratory for further testing based on validity problems).

- All urine specimens with initial validity test result of questionable validity at an onsite licensee testing facility will receive test results of adulterated, substituted, dilute, or invalid after initial and confirmatory validity testing at an HHS-certified laboratory.

- All FFD programs choose to test dilute specimens according to the optional provisions in § 26.163(a)(2). That is, any specimen with an initial drug test result equal to or greater than 50 percent of the cutoff calibrator will receive confirmatory LOD drug testing.

- Percentage of dilute specimens that test positive for drug(s) during initial testing and at confirmatory LOD testing: 33 percent.

- For all urine specimens with validity test results of invalid, the analysis assumes that a second specimen is collected under direct observation.

- Percentage of specimens collected under direct observation as a result of an initial specimen with an invalid test result that test positive for drugs (as discussed in the assumptions below):[6] 33 percent.

- Percentage of urine specimens with confirmed positive drug, and/or adulterated or substituted validity test result retested at the request of the donor at a second HHS-certified laboratory: 5 percent.

- Average amount of FFD manager time per appeal process for a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result: 12.5 hours.

- Average amount of worker time per appeal process for a confirmed positive drug

[6]A second specimen is collected under direct observation for donors that have an initial specimen with an invalid test result to reduce the probability that their second specimen will be altered (e.g., use of adulterants) and therefore, the drug use that was attempted to be masked during the initial specimen donation will more likely be detected in the second specimen collected.

test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result appealed by some donors: 2.0 hours.

- Percentage of confirmed positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test results appealed by some donors: 1 percent.

- Number of laboratory technicians per licensee testing facility: 4.

- Length of laboratory technician training course: 4 hours.

- Number of laboratory technician training courses per licensee testing facility: 1.

- Cost per laboratory technician training course conducted by a commercial vendor at a licensee testing facility: $500.00.

**26.133 Cutoff levels for drugs and drug metabolites**

This section revises former requirements in Section 2.7(e)(1) in Appendix A to Part 26, which pertained to the initial cutoff levels for drugs (marijuana, cocaine, opiate, phencyclidine, amphetamines). The final rule will lower the initial cutoff level for marijuana metabolites from 100 ng/mL to 50 ng/mL. FFD programs using onsite testing facilities will incur annual incremental costs as a result of the more stringent testing cutoff level, which will increase the number of positive drug tests for marijuana.[7] The additional costs will consist of the costs of initial and confirmatory drug testing at an HHS-certified laboratory, labor costs for the MRO and FFD personnel activities resulting from confirmed positive drug test results, the costs of retesting specimens at a second HHS-certified laboratory at the request of some donors, and the costs of the appeals process for some positive test results that donors choose to contest. The final rule will also raise the initial cutoff level for opiate metabolites from 300 ng/mL to 2,000 ng/mL. FFD programs using onsite licensee testing facilities will realize annual incremental savings as a result of the less stringent testing cutoff level, which will substantially reduce the number of positive opiate drug tests that MROs ultimately verify as negative. Savings are associated with eliminating specimen testing costs at an HHS-certified laboratory, labor costs of the MRO and FFD personnel activities resulting from positive drug tests results, the costs of retesting specimens at a second HHS-certified laboratory at the request of some donors, and the cost of the appeals process for some positive test results that donors choose to contest.

*Annual cost per FFD program with an onsite licensee testing facility* for additional confirmed positive marijuana drug tests is estimated as the sum of the following:

[7]The analysis over-estimates the costs of additional confirmed positive marijuana test results due to the lower initial cut-off level (50 ng/mL) because some licensees may already be testing to the cut-off level.

- Cost for initial and confirmatory drug tests at HHS-certified laboratories

  $(NUM_{marijuana} \times PERI_{marijuana} \times COST_{HHS\ validity\ \&\ drug\ testing}) \times NUM_{reactors}$

- Cost for actions subsequent to positive confirmatory marijuana drug test results from the HHS-certified laboratory

  $(NUM_{marijuana} \times PERI_{marijuana} \times COST_{subsequent\ actions}) \times NUM_{reactors}$

- Cost for retesting specimens with confirmed positive marijuana drug test results at a second HHS-certified laboratory at the request of some donors

  $(NUM_{marijuana} \times PERI_{marijuana} \times PER_{retest} \times COST_{retest}) \times NUM_{reactors}$

- Cost of appeals process for confirmed positive marijuana test results that some donors choose to contest

  $(NUM_{marijuana} \times PERI_{marijuana} \times PER_{appeal}) \times [(HOURS_{FFD\ manager} \times WAGE_{FFD\ manger}) + HOURS_{Worker} \times WAGE_{Worker})] \times NUM_{reactors}$

*Annual saving per FFD program with an onsite licensee testing facility* for fewer confirmed positive opiate drug test results is estimated as the sum of the following:

- Saving from fewer specimens with positive opiate drug tests requiring testing at HHS-certified laboratories

  $(NUM_{opiate} \times PERD_{opiate} \times COST_{HHS\ validity\ \&\ drug\ testing}) \times NUM_{reactors}$

- Saving from fewer specimens with confirmed positive opiate drug test results associated subsequent actions

  $(NUM_{opiate} \times PERD_{opiate} \times COST_{subsequent\ actions}) \times NUM_{reactors}$

- Saving from fewer confirmed positive opiate drug test specimens retested at another HHS-certified laboratory at the request of donors

  $(NUM_{opiate} \times PERD_{opiate} \times PER_{retest} \times COST_{retest}) \times NUM_{reactors}$

- Saving from fewer appeals for some confirmed positive opiate drug test results

  $(NUM_{opiate} \times PERD_{opiate} \times PER_{appeal}) \times [(HOURS_{FFD\ manager} \times WAGE_{FFD\ manger}) + HOURS_{Worker} \times WAGE_{Worker}] \times NUM_{reactors}$

| Parameter | Description |
|---|---|
| $NUM_{marijuana}$ | Number of confirmed positive marijuana drug test results per reactor per year under the former rule (as discussed in Appendix 2, Exhibit A2-12) |
| $PERI_{marijuana}$ | Percentage increase in positive marijuana drug tests results due to the more stringent cutoff level in the final rule (as discussed in the assumptions below) |
| $COST_{HHS\ validity\ \&\ drug\ testing}$ | Cost of preparing and shipping a urine specimen with an initial positive drug test result to an HHS-certified laboratory and the cost of validity and drug testing at the HHS-certified laboratory (as discussed in Appendix 2, Exhibit A2-13) |
| $COST_{subsequent\ actions}$ | Labor costs associated with MRO and FFD program personnel activities and administrative actions resulting from a confirmed positive drug test result (as discussed in Appendix 2, Exhibit A2-13) |
| $PER_{retest}$ | Percentage of urine specimens with confirmed positive drug test results retested at the request of the donor at a second HHS-certified laboratory (as discussed in the assumptions below) |
| $COST_{retest}$ | Cost of specimen retesting at second HHS-certified laboratory including specimen preparation and shipping costs (as discussed in Appendix 2, Exhibit A2-13) |
| $NUM_{opiate}$ | Number of confirmed positive opiate drug test results per reactor per year under former rule (as discussed in Appendix 2, Exhibit A2-12) |
| $PERD_{opiate}$ | Percentage decrease in confirmed positive opiate drug test results due to the higher cutoff level in the final rule (as discussed in the assumptions below) |
| $PER_{appeal}$ | Percentage of confirmed positive drug test results appealed by some donors (as discussed in the assumptions below) |
| $HOURS_{FFD\ manager}$ | Average amount of FFD manager time per appeal process for a confirmed positive drug test result (as discussed in the assumptions below) |
| $WAGE_{FFD\ manager}$ | FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11) |
| $HOURS_{Worker}$ | Average amount of worker time per appeal process for a confirmed positive drug test result (as discussed in the assumptions below) |
| $WAGE_{Worker}$ | Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11) |
| $NUM_{reactors}$ | Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14) |

*Assumptions:*

- Changing the cutoff thresholds for marijuana and opiates will not result in a change in assay costs, nor will the changes require the upgrading of testing facility equipment. Testing facilities will have to purchase new standards and controls specific for the changes in the cutoff thresholds; however, the purchasing of standards and controls is a normal operations cost and will not result in an incremental change.

- FFD programs pay HHS-certified laboratories a per specimen cost, which includes both initial and confirmatory drug testing.

- Percentage increase in positive marijuana drug tests results due to the more

stringent cutoff level in the final rule: 40 percent.[8]

- Percentage decrease in confirmed positive opiate drug test results due to the higher cutoff level in the final rule: 75 percent.[9]

- Percentage of urine specimens with confirmed positive drug test results retested at the request of the donor at a second HHS-certified laboratory: 5 percent.

- Average amount of FFD manger time per appeal process for a confirmed positive drug test result: 12.5 hours.

- Average amount of worker time per appeal process for a confirmed positive drug test result: 2.0 hours.

- Percentage of confirmed positive drug test results appealed by some donors: 1 percent.

**26.135 Split specimens**

***Paragraph 26.135(a)***

No incremental costs or savings will result from this final paragraph, which restates without substantive change the former requirements in Section 2.7(j) in Appendix A to Part 26, which pertained to split-specimen handling, testing, and storage procedures. The revisions conform the former requirements with the terminology used in other parts of the final rule, but they do not change the meaning of the former requirements.

**Paragraph 26.135(b)**

This paragraph of the final rule restates and revises former requirements in Section 2.7(j) in Appendix A to Part 26, which specified the specimen shipping procedures for licensee testing facilities when notified that a donor has requested that a split specimen be tested by a second HHS-certified laboratory. The former requirement maintained that the licensee testing facility could forward the split specimen to a second HHS-certified laboratory on the same day that the laboratory receives notice that a donor has requested testing of their split specimen. The final paragraph relaxes the former requirement by providing one business day following the day of the donor's request for the specimen to be forwarded to a second HHS-certified laboratory (per

[8]The experience of HHS-certified laboratories when U.S. DOT changed the marijuana metabolite cutoff level from 100 ng/mL to 50 ng/mL increased the number of positive marijuana test results from 25-40 percent. Several licensees currently test for marijuana metabolites at the 50 ng/mL cutoff level. One licensee reported 49 additional positive test results over a two and one-half year period, (an increase of 57 percent over the 100 ng/ml cutoff level).

[9]Raising the initial cutoff level for opiate metabolites will almost eliminate poppy seed false positive results, and unless an individual consumes large prescribed doses of codeine based cough syrup or other cold prescriptions, the threshold will significantly reduce positive screening results for opiates due to legitimate use of prescribed cold and cough prescriptions.

§ 26.165(b) of the final rule). No incremental costs or savings will result from this final paragraph as it provides licensees with additional time to respond to a donor's request for specimen retesting, but does not change the required activity.

**Paragraph 26.135(c)**

There is no incremental cost or saving from this final paragraph as it clarifies former requirements in Section 2.7(h) in Appendix A to Part 26, which pertained to long-term frozen storage of positive, adulterated, substituted, and invalid urine specimens.

**26.137 Quality assurance and quality control**

**Paragraph 26.137(a)**

This paragraph of the final rule restates without substantive change the former requirements in Section 2.8(a) in Appendix A to Part 26, which describe the elements of a licensee testing facility quality assurance program.

**Paragraph 26.137(b)**

This paragraph of the final rule establishes performance testing and quality control requirements for validity screening tests conducted at licensee testing facilities. As discussed in § 26.131(a) of the analysis, the analysis assumes that no licensee testing facilities will conduct validity screening tests. However, given that the final rule in § 26.131(a) now requires validity testing of each urine specimen (either validity screening and/or initial validity testing) by licensee testing facility, compliance with this final paragraph or that of §§ 26.137(c) or (d) is a new requirement. No incremental costs or savings will result from this final paragraph because the analysis assumes that licensees will conduct initial validity tests. The costs for all licensee testing facility validity tests costs are included in § 26.137(d).

**Paragraph 26.137(c)**

This paragraph establishes that if a licensee testing facility conducts validity screening tests on urine specimens, for specimens with results of questionable validity, the licensee testing facility must either then perform initial validity testing or must send the specimens to an HHS-certified laboratory for additional validity testing. As discussed in § 26.131(a), the analysis assumes that no licensee testing facilities will conduct validity screening tests. Therefore, no incremental costs or savings will result from this final paragraph. However, given that the final rule in § 26.131(a) now requires validity testing of each urine specimen (either validity screening and/or initial validity testing) by each licensee testing facility, compliance with this final paragraph or that of §§ 26.137(b) or (d) is a new requirement.

**Paragraph 26.137(d)**

This paragraph of the final rule establishes the quality control requirements that analytical

equipment must meet in order to be used to perform initial validity tests and specifies the quality control samples that must be included in each analytical run. The incremental costs of initial validity testing (including quality control measures) are included in the per test cost to conduct initial validity testing, as discussed in connection with § 26.131.

**Paragraph 26.137(e)**

This paragraph of the final rule revises quality control requirements for initial drug tests that are performed at licensee testing facilities, as discussed in §§ 26.137(e)(1)–(8).

***Subparagraph 26.137(e)(1)***

There are no incremental costs or savings from this final subparagraph as it clarifies former requirements in Section 2.7(e)(1) in Appendix A to Part 26, which required licensee testing facilities to conduct initial drug tests using an immunoassay meeting the requirements of the Food and Drug Administration (FDA) for commercial distribution. This subparagraph also adds a new provision that prohibits non-instrumented immunoassay testing devices that are pending HHS/Substance Abuse and Mental Health Services Administration (SAMHSA) review and approval from being used for initial drug testing under this part. The subparagraph also adds a provision that licensees and other entities may not take management action against an individual based on any drug test results obtained from non-instrumented devices that may be used for validity screening tests. The new requirements in this subparagraph will result in no incremental costs or savings for licensee testing facilities because the provisions simply prohibit the use of specific analytical equipment and prevent management action based on non-instrumented devices.

***Subparagraph 26.137(e)(2)***

This subparagraph of the final rule establishes that negative urine specimens must be discarded or pooled for use in the licensee testing facility's internal quality control program, as long as the specimens are certified as drug-negative and valid by an HHS-certified laboratory. The analysis assumes that licensee testing facilities will choose the most cost-effective method of obtaining negative urine specimens to be used as their quality control testing specimens, and that licensee testing facilities already (1) purchase negative urine specimens directly from a vendor selling HHS-certified drug negative urine or from an HHS-certified laboratory, (2) pool the negative urine specimens analyzed at their testing facility and submit them to an HHS-certified laboratory for testing to certify that they are drug-negative. The final rule will not change these practices, so no incremental costs or savings will result.

***Subparagraph 26.137(e)(3)***

No incremental cost or saving will result from this final subparagraph as it affords licensee testing facilities the flexibility to conduct multiple initial drug tests for the same drug or drug class, provided that all tests meet the cutoffs and quality control requirements in this part.

***Subparagraph 26.137(e)(4)***

No incremental cost or saving will result from this final subparagraph, which restates former requirements in Section 2.8(b) in Appendix A to Part 26.

***Subparagraph 26.137(e)(5)***

This subparagraph of the final rule revises a former requirement in Section 2.8(b) in Appendix A to Part 26, which mandated that each licensee testing facility submit a "sampling" of urine specimens screening negative for drugs from each test run to an HHS-certified laboratory for additional drug testing to ensure that the drug testing process of the licensee testing facility is accurate, with no false negative tests results. This subparagraph revises the former requirement by clarifying that the term "sampling" means a minimum of 5 percent (or at least 1) of the drug test specimens screening negative for drugs from every analytical run. Some FFD programs using onsite licensee testing facilities may realize annual incremental savings resulting from this final rule revision. Licensee testing facilities that submit a sample of negative drug test specimens from each analytical run below the 5 percent maximum level will not be affected by this final subparagraph because current practice already meets the final rule requirement. Even though some onsite licensee testing facilities may be submitting more than 5 percent of negative drug test specimens per analytical run to an HHS-certified laboratory, an accurate estimate on savings is not possible due to a lack of data on current onsite licensee testing facility practices.

***Subparagraph 26.137(e)(6)***

This subparagraph of the final rule extends to licensee testing facilities the former requirements in Section 2.8(c) in Appendix A to Part 26, which mandated that HHS-certified laboratories must include a minimum of 10 percent of the total number of urine specimens in each analytical run as quality control samples. This subparagraph of the final rule also extends to licensee testing facilities the former requirements in Section 2.8(c) in Appendix A to Part 26, which pertained to the quality control samples that must be included in each analytical run of initial drug tests performed by HHS-certified laboratories. The quality control samples must consist of: (1) specimen(s) certified to contain no drug (i.e., negative urine samples), (2) at least one positive control with drug(s) or drug metabolite(s) targeted at 25 percent above the cutoff, (3) at least one positive control with drug(s) or drug metabolite(s) targeted at 25 percent below the cutoff, (4) a sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff, and (5) sample(s) that appear to be a donor specimen to the laboratory analysts. With regard to the quality control samples that must be included in each analytical run, this subparagraph imposes no incremental cost because licensee testing facilities are assumed to use appropriate control specimens in each analytical run, as specified by the manufacturer's operating manuals for drug testing equipment. However, the change in the composition of the blind performance testing samples results in an incremental cost per urine specimen analyzed to comply with this final paragraph.

The *annual cost per FFD program with onsite licensee testing facilities* is estimated as follows:

$(NUM_{specimens} \times COST_{specimen} \times PERI_{cost}) \times NUM_{reactors}$

| Parameter | Description |
|---|---|
| $NUM_{specimens}$ | Number of urine specimens analyzed per reactor per year for FFD programs with onsite licensee testing facilities (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12) |
| $COST_{specimen}$ | Cost per urine specimen to conduct drug testing as specified in the former requirements (as discussed in Appendix 2, Exhibit A2-11) |
| $PERI_{cost}$ | Percentage increase in the average urine specimen analysis cost based on the change in costs to comply with the quality control specimen testing requirements (as discussed in the assumptions below) |
| $NUM_{reactors}$ | Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14) |

*Assumptions:*

- Number of urine specimens analyzed per reactor per year for FFD programs with onsite licensee testing facilities is equivalent to the number of drug tests performed per reactor per year for FFD programs with onsite licensee testing facilities.

- Percentage increase in the average urine specimen analysis cost based on the change in costs to comply with the quality control specimen testing requirements [this includes the increase in costs per blind performance test specimen to comply with the inclusion of adulterated, substituted, dilute and invalid specimens as a part of the percentage of specimens as discussed in § 26.167(f) of Subpart G]: 10 percent.

***Subparagraph 26.137(e)(7)***

This subparagraph of the final rule extends to licensee testing facilities the former requirements in Section 2.8(c) in Appendix A to Part 26, which mandated that (HHS-certified) laboratories must implement procedures to ensure that carryover does not contaminate the testing of a donor's specimen. This subparagraph imposes no incremental cost and affords no savings because it is consistent with existing specimen handling procedures used by licensee testing facilities.

**Paragraph 26.137(f)**

This paragraph of the final rule clarifies that it is the licensees' responsibility to investigate errors in the testing of quality control samples, the testing of actual specimens, or the processing of management reviews and/or MRO reviews, as well as any other errors or matters that could reflect adversely on the licensees' testing process. The licensees' mandated responsibility also includes taking action to correct errors that are within the licensees' control. This analysis assumes that no incremental costs or savings will result from the final paragraph because licensees were formerly responsible [under a performance standard in Section 2.8(a) in Appendix

A to Part 26] for having "a quality assurance program which encompasses all aspects of the testing process."

**Paragraph 26.137(g)**

There is no incremental cost or saving from this final paragraph as it restates a former rule requirement in Section 2.7(o)(3)(i) in Appendix A to Part 26.

**Paragraph 26.137(h)**

This paragraph of the final rule clarifies and revises former requirements in Section 2.7(o)(2) in Appendix A to Part 26, which required licensee testing facilities to use "HHS-certified laboratory standards." The final rule relaxes the former requirements by permitting licensee testing facilities to use "stock standard solutions obtained from other laboratories, or standard solutions obtained from commercial manufacturers." This analysis assumes that any incremental saving from this final paragraph will be insignificant.

**26.139 Reporting initial validity and drug test results**

**Paragraph 26.139(a)**

No incremental cost or saving is estimated for this final paragraph, which restates without substantive change requirements in § 2.7(g)(2) in Appendix A to Part 26, as they relate to drug testing. Paragraph 26.131(a) of the final rule requires validity screening and/or initial validity test results. The new provisions in this paragraph add reporting requirements for negative and questionable validity test results for validity screening and initial validity tests. Except as permitted under paragraph 26.75(h), licensee testing facilities are prohibited from reporting positive test results from initial drug tests and results from validity screening or initial validity testing to licensee or other entity management. The new provisions in this final paragraph will result in no incremental costs or savings because the provisions prohibit communication of specific types of test results rather than require any specific activity. In addition, because licensee testing facilities already have established communication methods to transmit drug test results to licensee and FFD management, the inclusion of validity test results will result in an no incremental cost or saving.

**Paragraph 26.139(b)**

This paragraph of the final rule restates without substantive change a former requirement in § 26.24(d)(1), which limited access to initial drug test results to licensee testing staff, the MRO, the FFD manager, and EAP personnel (when appropriate). The final rule also permits the SAE to access initial drug test results. No incremental cost or savings will result from the final paragraph because it clarifies who is permitted access to test results.

**Paragraph 26.139(c)**

No incremental costs or savings will result from this final paragraph which restates the former requirements in Section 2.7(o)(5) in Appendix A to Part 26, which mandated that a licensee testing facility must have qualified personnel available to testify at proceedings against an individual based on urinalysis results.

**Paragraph 26.139(d)**

This paragraph of the final rule revises the former requirements in Section 2.7(g)(6) in Appendix A to Part 26, which specified that licensee testing facilities must provide a monthly statistical summary of urinalysis data to a licensee official responsible for coordinating the FFD program. The final paragraph only requires that licensee testing facilities must prepare the information required for the annual report that each FFD program must provide to NRC on an annual basis, as discussed in § 26.717 of the final rule. Therefore, licensee testing facilities will now prepare the statistical summary of urinalysis data only on an annual basis. Incremental savings will be realized by each FFD program due to the reduction in labor costs associated with the elimination of monthly statistical summary reports. Some of the savings will be offset by the labor costs associated with annual report preparation.

- *Annual saving per FFD program with onsite testing facilities* is estimated as follows:

$$(HOURS_{monthly\ report} \times WAGE_{laboratory\ supervisor} \times NUM_{monthly\ reports} \times NUM_{facilities}) - (HOURS_{annual\ report} \times WAGE_{laboratory\ supervisor} \times NUM_{facilities})$$

| Parameter | Description |
|---|---|
| $HOURS_{monthly\ report}$ | Time for a laboratory supervisor per licensee testing facility to prepare a monthly statistical summary report of urinalysis testing data (as discussed in the assumptions below) |
| $WAGE_{laboratory\ supervisor}$ | FFD manager wage rate (as discussed in Appendix 2) |
| $NUM_{monthly\ reports}$ | Number of monthly reports per FFD program per year |
| $HOURS_{annual\ report}$ | Time for a laboratory supervisor per licensee testing facility to prepare an annual statistical summary report of urinalysis testing data (as discussed in the assumptions below) |
| $NUM_{facilities}$ | Number of licensee testing facilities per FFD program (as discussed in Appendix 2) |

Assumptions:

- Time for a laboratory supervisor per licensee testing facility to prepare a monthly statistical summary report of urinalysis testing data: 1.5 hours.

- Time per report for a laboratory supervisor to prepare an annual statistical summary report of drug testing data: 4 hours.

**Paragraph 26.139(e)**

This paragraph of the final rule revises the former requirements in Section 2.7(g)(7) in Appendix A to Part 26, which pertained to the reporting of drug testing results to NRC. Under the former rule, if a licensee conducted drug testing using more stringent cutoff levels than required in 10 CFR Part 26, the licensee had to report the drug test results for the cutoff levels mandated by Part 26, as well as more stringent levels. The final rule relaxes the reporting requirements and only requires licensees to report in the annual report to NRC the drug testing information for either the cutoff levels specified in § 26.31(d)(1) or for any more stringent cutoff levels used by the FFD program. In addition, if the licensee tests for additional drugs beyond those specified in § 26.31(d)(1), this final paragraph adds a requirement that the annual report also include the number of positive test results and the cutoff levels used for those additional drugs and drug metabolites. No incremental costs or savings are estimated for the final paragraph because licensee testing facilities conducting drug testing using more stringent cutoff levels and/or testing for additional drugs beyond Part 26 requirements already tabulate the necessary testing data under the former rule.

**Paragraph 26.139(f)**

This paragraph of the final rule adds a new requirement that the designated FFD program official use the available information from the licensee testing facility's validity and drug test results, the results of quality control testing performed at the licensee testing facility, and the results from testing the quality control samples that the licensee testing facility submits to the HHS-certified laboratory to evaluate continued testing program effectiveness and detect any local trends in drugs of abuse that may require management action or FFD program adjustments. No incremental costs or savings are estimated because this requirement is consistent with current oversight practices of existing FFD programs.