Subpart E: Collecting Specimens for Testing

26.81 Purpose and applicability

This section of the final rule imposes no incremental cost and affords no saving because it merely explains that Subpart E presents the requirements associated with collecting specimens for drug and alcohol testing by or on behalf of the licensees and other entities in § 26.3. This section also states that the requirements of this Subpart do not apply to specimen collections and alcohol tests that are conducted under the requirements of 49 CFR Part 40, "Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs," as permitted under §§ 26.4(j), 26.31(b)(2), and Subpart K.

26.83 Specimens to be collected

Paragraph 26.83(a)

This paragraph of the final rule revises the requirements in former § 26.24(g), which specified the types of specimens permitted to be analyzed for alcohol testing. Requirements in former § 26.24(g) of the former rule permitted the use of breath specimens for initial and confirmatory alcohol tests and blood specimens for additional confirmatory alcohol testing. The final rule eliminates the use of blood specimens for confirmatory alcohol testing which was permitted in former Section 2.2(d)(4) in Appendix A to Part 26. The final rule adds a new provision permitting the collection of oral fluids (in addition to breath) for initial alcohol tests. The use of oral fluids is a permissive relaxation of the former rule requirements providing licensees with flexibility in using an alternative specimen testing (saliva) method to conduct initial alcohol testing (see the discussion of § 26.91(a) of this analysis). Elimination of blood samples for confirmatory alcohol testing will result in minor licensee savings by eliminating the costs associated with collecting blood specimens from donors, analyzing blood specimens, lost worker productivity, and MRO time to review and communicate blood test results to the worker and FFD management.

The *annual saving per FFD program* is estimated as follows:

$$NUM_{blood} \times [(COST_{blood\ draw} + COST_{blood\ testing}) + (HOURS_{worker} \times WAGE_{worker}) + (HOURS_{MRO} \times WAGE_{MRO})]$$

Parameter	Description
NUM_{blood}	Number of blood tests per FFD program per year under the former rule (as discussed in the assumptions below)
$COST_{blood\ draw}$	Cost per blood test for a phlebotomist/RN to arrive at the onsite collection site and conduct a blood draw (as discussed in Appendix 2, Exhibit A2-13).
$COST_{blood\ testing}$	Cost per blood test for a laboratory to analyze a blood specimen for alcohol (as discussed in Appendix 2, Exhibit A2-13)
$HOURS_{worker}$	Hours of lost worker productivity resulting from receiving a blood test (as discussed in the assumptions below)

Parameter	Description
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-13)
$HOURS_{MRO}$	Hours of MRO time to review blood test results and communicate the results to the worker and FFD management (as discussed in the assumptions below)
$WAGE_{MRO}$	MRO wage rate (as discussed in Appendix 2, Exhibit A2-13)

Assumptions:

- Number of blood tests per FFD program per year under the former rule: 1.
- Hours of lost worker productivity per test resulting from receiving a blood test includes waiting time for phlebotomist/RN to arrive at the onsite collection site, conduct a blood draw, and complete paperwork: 45 minutes.
- Hours of MRO time to review blood test results and communicate the results to worker and FFD management: 45 minutes.
- Blood specimen is collected at the same collection site where the confirmatory evidential breath testing device (EBT) testing is conducted.

Paragraph 26.83(b)

This paragraph of the final rule imposes no incremental cost and affords no saving because it clarifies requirements in former § 26.24(f) which specified "urine drug testing" on all specimens at licensee testing facilities and/or HHS-certified laboratories. Since no other type of specimen is described in the former rule language as acceptable alternative for drug testing, this final paragraph simply clarifies the former rule requirements.

26.85 Collector qualifications and responsibilities

Paragraphs 26.85(a) and (b)

Paragraph 26.85(a) addresses urine collector qualifications and training requirements and paragraph 26.85(b) addresses alcohol collector qualifications and training. These final paragraphs revise requirements in former Section 2.2(d) in Appendix A to Part 26, which addressed training of collection site personnel. The former requirements specified collector training in maintaining the integrity of the specimen collection and transfer process, donor privacy issues, and appropriate collector conduct. The final rule adds requirements that collectors must be knowledgeable about Part 26, as well as the FFD policy and procedures of licensees and other entities, and must keep up to date with urine and alcohol collection procedures. It also requires all collectors to receive qualification training on problem collections and the correction of problems associated with collections.[1] FFD programs will incur

[1]All urine and breath collectors used by a licensee or other entity's collection site will receive re-training to

incremental costs associated with conducting one-time collector training classes and the labor costs for all collectors to attend a training class.[2]

The *one-time cost per FFD program* is estimated as follows:

$$NUM_{collectors} \times [(HOURS_{collector\ training} \times WAGE_{collector}) + COST_{training\ course})] \times NUM_{facilities}$$

Parameter	**Description**
$NUM_{collectors}$	Number of collectors per licensee facility (as discussed in the assumptions below)
$HOURS_{collector\ training}$	Length of training course (as discussed in the assumptions below)
$WAGE_{collector}$	Collection site personnel wage rate (as discussed in Appendix 2, Exhibit A2-11)
$COST_{training\ course}$	Cost of a commercial vendor to conduct an onsite collector training course per facility (as discussed in the assumptions below)
$NUM_{facilities}$	Number of facilities in a given FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Each facility uses a unique collection site.
- Each collector is trained to conduct urine and breath collections.
- Number of collectors per licensee facility: 4.
- Length of training course (includes urine and breath collections): 8 hours.
- Cost of collector training course for a commercial vendor to conduct onsite at a collection site: $1,000.

Paragraph 26.85(c)

This paragraph of the final rule revises the requirements in former Section 2.2(d)(2) in Appendix A to Part 26, which permitted medical professionals, technologists, and technicians to collect urine specimens without receiving training or demonstrating proficiency in specimen collections, as long as these collectors received the instructions in former Section 2.2(3) in Appendix A to Part 26 and perform collections in accordance with those instructions. The final paragraph adds a requirement that limits the persons excused from the training and demonstration of proficiency

meet the requirements in § 26.85(a) and (b) as well as to receive training on all new collection procedures resulting from the rule revision. Some of the urine collectors at a licensee collection site may be medical professionals, technologists, or technicians who are no longer exempted from the former rule requirement in Section 2.2(d)(2) in Appendix A due to the provision in § 26.85(c), and thus, may be receiving training for the first time.

[2] The analysis estimates no incremental cost for future training (e.g., due to normal employee turnover) because it is believed that new collectors already receive on-the-job training as part of their normal training activities given that the topics for qualification training are necessary for fulfilling job responsibilities (e.g., completing the custody-and-control form, shy bladder procedures, specimen integrity procedures, donor privacy protections).

requirements for specimen collections to medical professionals, technologists, or technicians who are not employed by the licensee's or other entity's FFD program and whose workplace is not at the licensee's or other entity's facility. This revision will increase the incremental cost per FFD program associated with the training costs for medical professionals, technologists, and technicians who serve as collectors, but who are no longer excused from training. The incremental cost resulting from additional training required under the new provision is discussed in connection with §§ 26.85(a) and (b).

Paragraph 26.85(d)

This paragraph of the final rule revises the former requirements in Section 2.7(o)(5) in Appendix A to Part 26, which required licensee testing facility and HHS-certified laboratory personnel to be available to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on positive drug or alcohol test results or adulterated or substituted test results reported by the licensee's testing facility or the HHS-certified laboratory. This final paragraph extends this requirement to qualified collection site personnel. The analysis estimates no incremental cost or saving will result from this final rule provision because the requirement is consistent with existing licensee and collection site actions with respect to personnel appearing for administrative or disciplinary proceedings related to a specimen collection.

Paragraph 26.85(e)

This paragraph of the final rule adds a new requirement that specifies the records that must be retained for collection site personnel. The paragraph requires that collection site personnel files include each individual's resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluations and advancement; incident reports, if any; results of tests that establish employee competency for the position he or she holds; and appropriate data to support determinations of honesty and integrity conducted in accordance with this part. This final paragraph extends to collection site personnel the records retention requirements in former Sections 2.5(f) and 2.6(c) in Appendix A to Part 26 for laboratory personnel and licensees' testing facility personnel, respectively. The analysis estimates no incremental cost will result from this final rule provision because it is assumed that these files are already kept for collection site personnel.

26.87 Collection sites

Paragraph 26.87(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies former requirements in Section 2.4(a) in Appendix A to Part 26, which related to designated collection sites.

Paragraph 26.87(b)

This paragraph of the final rule adds a new requirement that each collection site must provide

visual privacy while a donor and collector view the results of a breath alcohol test. The former requirements in Sections 2.4(g)(8) and 2.4(f) in Appendix A to Part 26 required only that a donor must be permitted to provide a urine specimen in the privacy of a stall or otherwise partitioned area. The requirement is estimated to result in no incremental cost or saving because collection sites that need to modify collection procedures to meet this new requirement can do so using readily available office supplies. For example, a piece of cardboard may be affixed over the EBT readout to prevent anyone other than the collector and donor from viewing test results.

Paragraph 26.87(c)

This paragraph of the final rule extends the requirement in former Section 2.7(m) in Appendix A to Part 26, which mandated that licensees must include in contracts for collection site services a provision that both NRC and licensees have the authority to conduct unannounced inspections and audits. The final paragraph extends the provisions in former Section 2.7(m) in Appendix A to other entities and their contracts for collection site services. The incremental costs associated with modifying other entity contracts with collection sites is discuss in connection with § 26.27(a).

Paragraph 26.87(d)

This paragraph of the final rule clarifies requirements in former Section 2.4(c) in Appendix A to Part 26 regarding collection site security procedures. Final § 26.87(d)(2) provides examples of methods that may be used to assure the security of a collection site such as locking doors, using alarms, or visually monitoring the collection site, and clarifies that designated collection sites must be secure at all times. Former Section 2.4(c) instructed that "security procedures shall provide for the designated collection site to be secure" while the former requirement in Section 2.4(c)(1) required that for specimen collections in a public rest rooms, the rest rooms be posted against access during the collection process. This paragraph of the final rule imposes no incremental cost and affords no saving because it clarifies former requirements by providing examples of methods to secure a collection site, but does not prescribe how the facility is to be secured.

Paragraph 26.87(e)

This section of the final rule discusses collection procedures that urine collectors must follow prior to and after a specimen collection to deter and detect instances where a donor attempts to adulterate, dilute, or substitute their urine specimen.

Subparagraph 26.87(e)(1)

This subparagraph amends the former requirement in Section 2.4(g)(1) in Appendix A to Part 26, which mandated the addition of toilet bluing agents to the water in the toilet tank in the enclosure where a urine specimen collection is conducted. By contrast, the final rule provides added flexibility for collection sites to use coloring agents other than blue (excluding yellow). This paragraph of the final rule imposes no incremental cost and affords no saving because many

similarly priced coloring agents existing on the market today that can meet the provision.

Subparagraph 26.87(e)(2)

This subparagraph imposes no incremental cost and affords no saving because it restates a former requirement in Section 2.4(g)(1) in Appendix A to Part 26, which required that sources of water present in an enclosure used for a specimen collection must be secured or monitored to detect and prevent specimen dilution.

Subparagraph 26.87(e)(3)

This subparagraph establishes a new provision under which a urine collector, before each collection, must inspect and secure or remove from the privacy enclosure all chemicals and products that could be used by a donor to adulterate their urine specimen. This subparagraph imposes no incremental cost or saving because it is consistent with existing collection site security procedures.

Paragraph 26.87(f)

This paragraph restates and clarifies former requirements in Section 2.4(c)(1)–(2) in Appendix A to Part 26 regarding procedures for collecting urine specimens at locations other than designated collection sites (e.g., public restroom, on-site restroom, hospital examining room). In addition, as described in the subparagraph discussions below, several of the revised subparagraphs include new provisions. However, no incremental costs or savings will result from the provisions in this final paragraph because urine specimen collections at non-designated collection sites are rare events (i.e., they apply to only some post-event tests and some for-cause tests).

Subparagraph 26.87(f)(1)

This subparagraph of the final rule adds a new provision to permit an individual to be assigned to prevent unauthorized access to a public restroom being used during a urine collection. The final rule also includes a requirement from former Section 2.4(c)(1) in Appendix A to Part 26 that a sign may be posted to prevent unauthorized access. No incremental cost or saving will result from this revised subparagraph because the new provision is a relaxation, permitting an alternative method to prevent unauthorized access to a public restroom.

Subparagraph 26.87(f)(2)

This subparagraph of the final rule revises the requirement in Section 2.4(g)(10) in Appendix A to Part 26 of the former rule that the collector add a toilet bluing agent in the bowl and any accessible toilet tank for a specimen collection conducted at a location other than a dedicated collection site. The revised subparagraph provides added flexibility by permitting collection sites to use coloring agents in addition to blue (excluding yellow) as described in final § 26.87(e)(1) and clarifies that the urine collector must add a water coloring agent to any accessible source of standing water within the enclosure where a donor is to provide a specimen. No incremental cost

or saving is estimated to result from these provisions which provide flexibility in the use additional types of coloring agents, and clarify existing collection practices to add coloring agents to accessible water sources within the privacy enclosure.

Subparagraph 26.87(f)(3)

This subparagraph of the final rule amends a former requirement in Section 2.4(g)(10) of Appendix A to Part 26 regarding the use of a same gender urine collector to accompany a donor into the area used for a specimen collection, if a multi-stalled bathroom is used. If a collector of the same gender is unavailable, the revised subparagraph provides additional flexibility by adding a provision that permits another person of the same gender who has been instructed in the requirements of Subpart E to assist in the collection. This revised subparagraph also adds a new requirement that the name of the same gender person must be documented on the custody-and-control form in situations where a same-gender collector is not available. No incremental cost or saving will result from this final subparagraph because the new provisions provide an alternative method to existing collection practices at non-dedicated collection sites.

Subparagraph 26.87(f)(4)

This subparagraph of the final rule imposes an additional inspection requirement to former Section 2.4(g) of Appendix to Part 26. The new requirement pertains to specimen collections at non-designated collection sites. Upon receiving a urine specimen from a donor, the collector must inspect the privacy enclosure where the specimen was provided to ensure that there is no evidence of a donor subversion attempt. This subpargraph also adds a requirement that the collector and not the donor flush the toilet at the completion of a specimen donation. A requirement in former Section 2.4(g)(10) permitted the donor to flush the toilet under certain circumstances. No incremental cost or saving is estimated to result from this revised subparagraph due to the rarity of collections at non-dedicated collection sites.

Subparagraph 26.87(f)(5)

This subparagraph of the final rule revises former requirements in Section 2.4(c)(2) in Appendix A to Part 26 which pertain to urine specimen collections conducted at non-dedicated collection facilities and which directed urine collectors to maintain physical control of donor urine specimens. The final provision relaxes the former requirement by permitting the collector to designate another individual to maintain custody of the specimen until it is shipped (i.e., in the case of an opposite gender collector who instructs a same gender individual to assist in a urine collection). This revised subparagraph also requires that, in the case where the collector uses an individual to assist in the collection process, the individual's name must be documented on the custody-and-control form. No incremental cost or saving is estimated to result from this final subparagraph due to the rarity of collections at non-dedicated collection sites.

26.89 Preparing to collect specimens for testing

Paragraph 26.89(a)

This paragraph of the final rule revises former requirements in Section 2.4(g)(3) in Appendix A to Part 26 regarding the actions to take if a donor does not arrive at the collection site for drug and/or alcohol testing. The former requirement instructed the collection site staff to contact "the appropriate authority to obtain guidance on the action to be taken." The final paragraph adds a new requirement that mandates that FFD program management investigate and determine whether the absence or tardiness of a donor is an attempt to subvert the testing process and to take appropriate action when necessary. This revision is believed to be consistent with long-term licensee practice and, therefore, will not result in incremental costs or savings.

Paragraph 26.89(b)

Subparagraphs 26.89(b)(1)–(2)

The subparagraphs revise former requirements in Section 2.4(g)(2) in Appendix A to Part 26, which describe the process for identifying a donor before collecting a specimen. Subparagraph 26.89(b)(1) clarifies former requirements pertaining to acceptable donor identification. Subparagraph 26.89(b)(2) now requires (rather than prohibits) a collection to proceed in cases where the donor does not produce acceptable identification, except for pre-access testing. The collector will now proceed with the specimen collection even without positively identifying the donor and will inform FFD program management that the employee could not be positively identified. FFD program management must then contact the individual's supervisor to verify in person the individual's identity, or if unavailable, take other steps to establish the individual's identity, and investigate the circumstances to determine whether the employee's behavior was an attempt to subvert the testing process. As a result, FFD programs may realize savings related to reduced worker productivity losses because workers will no longer have to leave the collection site, obtain appropriate identification, and return to the collection site for a test. Management time is not expected to change based on whether the manager's investigation occurs prior to or subsequent to the collection, in accordance with the former and final rules, respectively.

Subparagraph 26.89(b)(2) also adds a provision prohibiting a specimen collection in these cases if the test is a pre-access test. The analysis estimates no incremental cost or saving will result from this provision due to the rarity of these situations.

The *annual saving per FFD program* resulting from § 26.89(b)(2) is estimated as follows:

$$NUM_{selected\ individuals} \times PER_{no\text{-}ID} \times (HOURS_{worker} \times WAGE_{worker}) \times NUM_{reactors}$$

Parameter	**Description**
$NUM_{selected\ individuals}$	Number of individuals selected for drug and alcohol testing per reactor per year (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12)
$PER_{no\text{-}ID}$	Percentage of individuals without identification (as discussed in the assumptions below)
$HOURS_{worker}$	Time a donor without identification would spend to leave the collection site, obtain appropriate identification, and return to the collection site for drug and alcohol

Parameter	Description
	testing (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:

- Number of individuals selected for drug and alcohol testing per reactor per year is equivalent to the number of drug tests conducted per reactor per year (a drug and alcohol test is conducted each time an individual is tested). This assumes that each individual selected for testing is actually tested.

- Percentage of individuals without identification: 1 percent.
  The analysis assumes only 1 percent because employees subject to FFD program requirements must have identification with them at all times while at a licensed facility and, therefore, cases where an employee does not have adequate identification are rare.

- Time a donor without identification would spend to leave the collection site, obtain appropriate identification, and return to the collection site for drug and alcohol testing: 45 minutes.

- FFD management will incur no incremental costs or savings related to the final rule revisions. The analysis assumes that, under the former rule, the collection site notified FFD management after an employee arrived for a specimen collection without adequate identification, and FFD management investigated the situation with the employee. The final rule requires the collection site to contact FFD management after completing a test, but the activities and time required of the FFD management would be similar.

Subparagraph 26.89(b)(3)

This subparagraph restates the former requirements in Sections 2.4(g)(4) and (g)(23)(ii) in Appendix A to Part 26 with the exception of the requirement for the collector to direct the donor to list on the chain-of-custody form the prescription medications and over-the-counter (OTC) preparations taken within 30 days prior to their urine specimen collection. This revised subparagraph now prohibits the donor from listing prescription medications and OTC preparations recently used. This revised subparagraph also adds a new requirement for the collector to explain the testing procedure to each donor. Each FFD program will recognize incremental savings per urine collection resulting from the reduced time of the collection process due to the elimination of the donor listing medications and OTC preparations on the custody-and-control form. Theses savings are offset to a small extent by the increase in time related to the collector describing the testing process to each donor. Overall, a reduction in lost worker

productivity and reduced collector wages will be realized by FFD programs.[3]

The *annual saving per FFD program* is estimated as follows:

$$NUM_{collections} \times [(HOURS_{saved} - HOURS_{added}) \times (WAGE_{worker} + WAGE_{collector})] \times NUM_{reactors}$$

Parameter	Description
$NUM_{collections}$	Number of urine collections per reactor per year (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12)
$HOURS_{saved}$	Time saved per average collection because the donor does not list medications on the chain-of-custody form (as discussed in the assumptions below)
$HOURS_{added}$	Time added per average collection for the collector to explain the testing process to the donor (as discussed in the assumption below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$WAGE_{collector}$	Collection site personnel 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:

- Number of urine collections per reactor per year is equal to the number of drug tests per reactor per year.
- Time saved per average collection because the donor does not list medications on the CCF: 2 minutes.
- Time added per average collection for the collector to explain the testing process to the donor: 45 seconds.

Paragraph 26.89(c)

This paragraph of the final rule adds a new requirement directing the collector to inform the donor that, if the donor refuses to cooperate in the specimen collection process (including but not limited to, behaving in a confrontational manner that disrupts the testing process; admitting to the collector that he or she adulterated or diluted the specimen; is found to have a device, such as a prosthetic appliance, the purpose of which is to interfere with providing an actual urine specimen; or leaving the collection site before all of the collection procedures are completed) will be considered as a refusal to test. No incremental cost or saving is estimated to result from this final paragraph because providing the directions to the donor will only take seconds per collection, and the number of instances in which a donor will leave the collection site before

[3]In order to capture total costs and savings, the analysis assumes that savings incurred by any offsite collection sites are passed back to licensees (i.e., through lower costs per collection). This assumption depends on the degree to which the offsite collection site industry is price competitive. To the extent that it is not price competitive, savings will accrue as estimated, but will benefit the offsite collection site rather than licensees (i.e., offsite collection sites will recognize savings in labor costs because of the reduced collection time, but will not reduce the cost per collection charged to the licensee).

testing or will refuse to cooperate with the collection process will be very low due to the severity of the consequences.

Paragraph 26.89(d)

This paragraph restates former requirements in Section 2.4(e) in Appendix A to Part 26 which require that a collector only conduct one urine specimen collection at a time and defines when a collection process is complete, that is, when the donor has left the collection site.

26.91 Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use

Paragraph 26.91(a)

This paragraph of the final rule expands the acceptable breath alcohol testing devices beyond the former requirements in § 26.24(g). The final paragraph permits FFD programs to conduct initial tests for alcohol using NHTSA-certified alcohol screening devices (ASDs), including devices that test specimens of oral fluids or breath, that are on the NHTSA Conforming Products List (CPL). This provision affords licensees added flexibility in conducting initial tests for alcohol. However, because an EBT compliant with § 26.91(c) is required for confirmatory tests, the ability to use ASDs does not eliminate the need for an evidential breath testing device (EBT). The analysis assumes that licensees, in order to simplify their testing and training procedures, will conduct alcohol testing using only EBTs under normal circumstances, and that licensees will use ASDs only when a screening test must be conducted at a non-standard location (e.g., in the case of some post-event tests or possibly some for-cause tests). Because the need to conduct tests at non-standard locations is infrequent, the analysis assumes that any costs associated with the use of ASDs are insignificant to the analysis.

Paragraph 26.91(b)

This paragraph of the final rule adds a new requirement that all EBTs used to conduct confirmatory alcohol testing must meet the specific functionalities (e.g., provide a printed result for each breath test, test an air blank) as stated in § 26.91(c). This final paragraph also revises former requirements in § 26.24(g) and Section 2.4(g)(18) in Appendix A to Part 26 which mandated the use of two different EBTs for initial versus confirmatory alcohol testing. This final paragraph permits licensees to use a single EBT for both initial and confirmatory breath alcohol testing if the EBT meets the specifications in § 26.91(c). This final paragraph will result in an incremental one time cost for some FFD programs to purchase EBTs (along with necessary calibration equipment) meeting the specifications in § 26.91(c) for confirmatory breath alcohol testing, along with the one time cost to train breath alcohol collectors in the use of the new EBTs. Incremental annual costs incurred by FFD programs that purchase EBTs to comply with § 26.91(c) will consist of the cost to purchase calibration equipment to conduct quality control checks on the new EBTs.

One time costs per FFD program are estimated as the *sum* of the following*:*

- Purchase EBTs meeting the specifications in § 26.91(c):

  $COST_{EBT} \times NUM_{new\ EBTs} \times PER_{purchase\ EBT} \times NUM_{facilities}$

- Purchase a regulator used in calibrating new EBT equipment[4]:

  $COST_{regulator} \times PER_{purchase\ EBT} \times NUM_{facilities}$

- Breath alcohol collector training on use of new EBTs:

  $[COST_{training\ course} + (NUM_{collectors} \times (HOURS_{collector\ training} \times WAGE_{collector}))] \times NUM_{facilities} \times PER_{purchase\ EBT}$

The *annual cost per FFD program* is estimated as follows:

- Purchase calibration device for new EBTs:

  $COST_{calibration\ device} \times PER_{purchase\ EBT} \times NUM_{facilities}$

Parameter	**Description**
$COST_{EBT}$	Cost of an EBT compliant with § 26.91(c) (as discussed in Appendix 2, Exhibit A2-8)
$NUM_{new\ EBTs}$	Number of new EBTs compliant with § 26.91(c) purchased per facility (as discussed below and in Appendix 2, Exhibit A2-8)
$PER_{purchase\ EBT}$	Percentage of collection sites that will purchase an EBT meeting the specifications in § 26.91(c) (as discussed in the assumptions below)
$COST_{regulator}$	Cost of purchasing a regulator which attaches the calibration canister to the EBT (as discussed in the assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{training\ course}$	Cost of EBT manufacturer to conduct an onsite training course per collection site (as discussed in the assumptions below)
$NUM_{collectors}$	Number of breath alcohol collectors per collection site (as discussed in Appendix 2, Exhibit A2-8)
$HOURS_{collector\ training}$	Length of training course (as discussed in the assumptions below)
$WAGE_{collector}$	Collection site personnel wage rate (as discussed in Appendix 2, Exhibit A2-11)
$COST_{calibration\ canister}$	Cost of purchasing a calibration canister for quality control checks on new EBTs compliant with § 26.91(c) (as discussed in the assumptions below and in Appendix 2, Exhibit A2-13)
$NUM_{facilities}$	Number of facilities per FFD program (as discussed in Appendix 2, Exhibit A2-14)

[4]A regulator is a piece of equipment used to attach a calibration canister to an EBT in order to conduct quality control checks. One regulator can calibrate multiple EBTs.

Assumptions:

- Each facility uses one collection site.
- Percentage of collection sites that will purchase an EBT meeting the specifications in § 26.91(c): 50 percent.[5]
- Each collection site that purchases an EBT meeting the specifications in this § 26.91(c) will purchase one EBT.
- The EBTs purchased by any given collection site will be of the same manufacturer make and model and therefore, only one breath collector training class and only one regulator will be needed.
- Each calibration canister provides enough product to calibrate one EBT for two year of use. The annual cost of the calibration canister is the price of the canister divided by 2 years.

Paragraph 26.91(c)

This paragraph of the final rule establishes the required functionalities that an EBT must have to be used to conduct confirmatory alcohol testing. The incremental costs associated with some licensees purchasing EBTs meeting the functionalities in this final paragraph are described in § 26.91(b). This final paragraph also revises the former requirements in § 26.24(g) and Section 2.4(g)(18) in Appendix A to Part 26 which required the use of different EBTs for initial and confirmatory alcohol tests. This provision provides flexibility for licensees using an EBT meeting the criteria specified in this final paragraph by permitting the use of the same EBT for both initial and confirmatory tests. Incremental savings for FFD programs with collection sites that use EBTs meeting the specifications in this final paragraph will consist of a reduction in the time between conducting initial and confirmatory breath alcohol tests.

Annual saving per FFD program is estimated as follows:

$$NUM_{confirmatory\ alcohol\ tests} \times PER_{new\ EBT} \times [HOURS_{saved} \times (WAGE_{worker} + WAGE_{collector})] \times NUM_{reactors}$$

Parameter	Description
$NUM_{confirmatory\ alcohol\ tests}$	Number of confirmatory alcohol tests per reactor per year (as discussed in Appendix 2, Exhibit A2-12)

[5] The 50 percent estimate is based on an NEI industry survey (May 2004) in which 21 FFD programs that represent 32 facilities reported on the number of EBTs that would be purchased to meet the requirements in 26.91(c). Of the 32 facilities, 24 facilities had EBTs compliant with §26.91(c) and would not purchase any new equipment. The remaining 8 facilities in the survey reported that 16 new EBTs would be purchased. As an industry, 16 new EBTs would be purchased for the 32 facilities surveyed, or an average of 0.5 EBTs per facility. Therefore, 50 percent of collection sites will purchase one EBT.

Parameter	Description
$PER_{new\ EBT}$	Percentage of collection sites that will use an EBT meeting the specifications in paragraph 26.91(c) for both initial and confirmatory alcohol tests (as discussed in the assumptions below)
$HOURS_{saved}$	Time per test to set-up a second EBT (locate the EBT, turn on the equipment) to conduct confirmatory testing as required under the former requirements in § 26.24(g) and § 2.4(g)(18) (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$WAGE_{collector}$	Collection site personnel 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:

- Number of confirmatory alcohol tests conducted per reactor per year is equivalent to the number of confirmatory positive alcohol test results per reactor per year.

- Time per test to set-up a second EBT to conduct confirmatory testing: 2 minutes. If a second EBT is needed, the collector must prepare the second EBT to be used for the confirmatory test.

- Percentage of collection sites that will use an EBT meeting the specifications in paragraph 26.91(c) for both initial and confirmatory alcohol test: 50 percent.

Paragraph 26.91(d)

This paragraph establishes the quality assurance and quality control requirements for ASDs. The final paragraph requires that licensees using ASDs must implement the quality assurance plan (QAP) submitted by the manufacturer to NHTSA. No incremental cost or saving is estimated to result from this provision because the use of ASDs provides an alternative to former requirements for conducting initial alcohol testing.

Paragraph 26.91(e)

This paragraph establishes a new requirement that licensees and other entities implement the quality assurance and quality control requirements for EBTs as described in the most recent quality assurance plan (QAP) submitted by each EBT manufacturer to NHTSA. Adherence to the QAP for an EBT is consistent with existing collection site practices given that the specifications in the QAP are necessary for normal equipment operation and for accurate and defensible results. This paragraph adds an optional provision for collection sites to conduct an external calibration check immediately after a positive test result. This provision is optional and will not result in any incremental cost or saving given that the number of positive tests is infrequent.

26.93 Preparing for alcohol testing

Paragraph 26.93(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it clarifies former requirements in Section 2.4(g)(18) in Appendix A to Part 26 regarding testing procedures for conducting initial breath alcohol tests, including a mandatory 15 minute waiting period if the donor has consumed any potential sources of mouth alcohol (e.g., breath fresheners) or has ingested or expelled any other substances (e.g., via eating, smoking, regurgitation of stomach contents from vomiting or burping). This paragraph of the final rule also adds several requirements as described in the subparagraph discussions below.

Subparagraph 26.93(a)(1)

This subparagraph of the final rule clarifies a former requirement in Section 2.4(g)(18) in Appendix A to Part 26. This final subparagraph also adds a new requirement for a collector to instruct the donors to avoid eating, drinking, belching, or putting anything in their mouth during the collection process. No incremental cost or saving will result from this final subparagraph because this activity will only take seconds to complete.

Subparagraphs 26.93 (a)(2)–(3)

These subparagraphs of the final rule clarify former breath collection requirements in Section 2.4(g)(18) in Appendix A to Part 26 which directed the collector to proceed with a collection if a donor has not consumed any substance prior to the test. Subparagraph 26.93(a)(3) adds a requirement for the breath collector to inform the donor that a mandatory 15-minute waiting period is necessary to prevent an accumulation of mouth alcohol from leading to an artificially high breath alcohol reading if the donor has consumed a substance (e.g., ate, smoked) or belched prior to a test. No significant incremental cost or saving will result from § 26.93(a)(2) as it restates former requirements, nor from § 26.93(a)(3), which require an activity that will only take seconds to complete.

Subparagraph 26.93(a)(4)

This subparagraph of the final rule adds a new requirement to the former breath collection procedures in Section 2.4(g)(18) in Appendix A to Part 26. This final subparagraph requires that breath alcohol collectors explain to each donor, when needed, that during the mandatory 15-minute waiting period it is to the donor's benefit to avoid the activities described by the collector in § 26.93(a)(1). No significant incremental cost or saving will result from this final subparagraph because this activity is conducted during the mandatory waiting period.

Subparagraph 26.93(a)(5)

This subparagraph of the final rule adds a new requirement to the former breath collection procedures in Section 2.4(g)(18) in Appendix A to Part 26. The new provision adds a

requirement for breath alcohol collectors to inform each donor who indicated that they have demonstrated behaviors described in § 26.93(a)(1) within 15-minutes before an initial alcohol test, that an initial test (and confirmatory test, when necessary) will be performed at the end of the 15-minute waiting period, even if the donor did not follow the instructions given by the collector during the waiting period. No significant incremental cost or saving will result from this final subparagraph because this activity is conducted during the mandatory waiting period.

Subparagraph 26.93(a)(6)

This subparagraph of the final rule adds a new requirement to the former breath collection procedures in Section 2.4(g)(18) in Appendix A to Part 26. The new provision requires that breath collectors document that directions regarding the breath alcohol collection process were communicated to each donor. This activity will result in no significant incremental cost or saving because the activity will take only seconds to complete (i.e., the collector notes on the testing form the phrase "instructions given to donor").

Paragraph 26.93(b)

This paragraph adds a new requirement to the former drug and alcohol testing procedures in § 26.24(a)(3). The new provision directs licensees to minimize delays in administering for-cause drug and alcohol tests. This final paragraph also adds a requirement that specifies the sequence of specimen testing in for-cause testing situations (i.e., requires alcohol testing be conducted before drug testing). The former rule did not specify the order that drug and alcohol testing was to be conducted in for-cause testing situations. No incremental cost or saving will result from the final paragraph because for-cause drug and/or alcohol testing is already required by the former requirement in § 26.24(a)(3). The final paragraph only specifies that delays in testing should be minimized and specifies the sequence for conducting for-cause alcohol and drug testing.

26.95 Conducting an initial test for alcohol using a breath specimen

This section, including paragraphs (a)–(c), revises former requirements in Section 2.4(g)(18) in Appendix A to Part 26, which mandated the collection of two breath specimens for each screening alcohol test using an EBT. The tests must be conducted no less than 2 minutes and no more than 10 minutes apart. Paragraph 26.95(c) reduces the number of breath specimens collected from two to one unless problems arise. FFD programs will realize a reduction in alcohol testing costs due to a decrease in the duration of the testing process, reducing equipment costs (using fewer exhalent tubes), decreasing worker productivity losses, and reducing collector labor costs.[6]

The *annual saving per FFD program* resulting from § 26.95(c) is estimated as follows:

[6] In order to capture the total costs and savings, the analysis assumes that savings incurred by offsite collection sites are passed back to licensees (i.e., lower costs per collection). This assumption depends on the degree to which the offsite collection site industry is price-competitive. To the extent that it is not price competitive, savings will accrue as estimated, but will benefit the offsite collection site rather than licensees (i.e., offsite collection sites will realize savings in labor costs because of the reduced collection time, but will not reduce the cost per collection charged to licensees).

$NUM_{alcohol\ tests} \times [HOURS_{saved} \times (WAGE_{worker} + WAGE_{collector}) + COST_{exhalent\ tube}] \times NUM_{reactors}$

Parameter	Description
$NUM_{alcohol\ tests}$	Number of alcohol tests per reactor per year (as discussed in Appendix 2, Exhibit A2-12)
$HOURS_{saved}$	Reduction in collection time from one fewer breath collection per initial screening test (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$WAGE_{collector}$	Collection site personnel wage rate (as discussed in Appendix 2, Exhibit A2-11)
$COST_{exhalent\ tube}$	Cost per exhalent tube (as discussed in Appendix 2, Exhibit A2-13)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Reduction in collection time resulting from one fewer breath collection per initial screening test: 2 minutes/60 minutes = 0.033 hours.

- Each breath specimen collection requires a new exhalent tube (i.e., for a screening test under the former regulations, two exhalent tubes would be used).

26.97 Conducting an initial test for alcohol using a specimen of oral fluids

This section, including paragraphs (a)–(e), establishes collection procedures for conducting initial alcohol tests using ASDs. The former requirements in § 26.24(g) only permit the collection of breath specimens (for initial and confirmatory alcohol tests) and blood specimens (for confirmatory alcohol testing). The use of ASDs provides licensees with flexibility in conducting alcohol testing by permitting the testing of an alternative specimen type (i.e., saliva) to breath for initial alcohol testing as discussed in § 26.91(a).

26.99 Determining the need for a confirmatory test for alcohol

Paragraph 26.99(a)

This paragraph of the final rule establishes that a breath alcohol concentration (BAC) of less than 0.02 percent constitutes a negative alcohol test result. This revision modifies former requirements in § 26.24(g) and Section 2.7(e)(1) in Appendix A to Part 26 which specified that a breath alcohol testing result of less than 0.04 is a negative test result. Incremental costs associated with the final paragraph are described in the discussion of § 26.99(b).

Paragraph 26.99(b)

This paragraph of the final rule revises former requirements in § 26.24(g) and Section 2.7(e)(1) in Appendix A to Part 26 by reducing the BAC of an initial alcohol test that requires a

confirmatory test from 0.04 percent to 0.02 percent. FFD programs will incur incremental costs because of an increase in the number of initial alcohol tests requiring confirmatory testing and the costs of FFD administrative actions resulting from additional confirmed positive alcohol test results. This final paragraph also adds a new provision that directs the collector to document the time of the initial breath alcohol test result (if 0.02 percent or greater) and inform the donor that a confirmatory test is required. The requirements to document the time of the test result and notify the employee that a confirmatory test must be performed are consistent with existing collection practices and will result in no incremental cost or saving.

The *annual cost per FFD program* is estimated as follows:

$$(NUM_{IPAT} \times PERI_{IPAT}) \times [(HOURS_{CAT} \times (WAGE_{worker} + WAGE_{collector}) + COST_{exhalent\ tube} + (HOURS_{FFD\ manager} \times WAGE_{FFD\ manager})] \times NUM_{reactors}$$

Parameter	**Description**
NUM_{IPAT}	Number of initial positive breath alcohol test (IPAT) results per reactor per year under the former requirements (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12)
$PERI_{IPAT}$	Percentage increase in the number of initial positive alcohol test (IPAT) results under the lower screening level BAC that remain positive after confirmatory testing (as discussed in the assumptions below)
$HOURS_{CAT}$	Time to conduct a confirmatory alcohol test under the final rule (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$WAGE_{collector}$	Collection site personnel wage rate (as discussed in Appendix 2, Exhibit A2-11)
$COST_{exhalent\ tube}$	Cost of an exhalent tube for a confirmatory alcohol test (as discussed in Appendix 2, Exhibit A2-13)
$HOURS_{FFD\ manager}$	Hours of FFD manager time associated with personnel activities and administrative actions resulting from a confirmed positive alcohol test result (as discussed in the assumptions below)
$WAGE_{FFD\ manager}$	FFD management 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:

- Number of initial positive breath alcohol test (IPAT) results per reactor per year under the former requirements in Part 26 is assumed to be equal to the number of confirmed positive alcohol tests under the former rule per reactor per year.

- Percentage increase in the number of initial positive breath alcohol test results under the lower screening level BAC that will remain positive after confirmatory testing: 20 percent.

- Time to conduct a confirmatory alcohol test under the final rule: 3 minutes.

- Hours of FFD manager time associated with personnel activities and administrative actions resulting from a confirmed positive alcohol test result (i.e., worker notification interview, paperwork, and administrative proceedings: 2.5 hours.

- All initial positive alcohol test results are confirmed positive.

26.101 Conducting a confirmatory test for alcohol

Paragraph 26.101(a)

This paragraph of the final rule revises former requirements in Section 2.4(g)(18) in Appendix A to Part 26, which relate to confirmatory alcohol testing. The final rule requires that a confirmatory alcohol test be conducted as soon as possible following an initial alcohol test result of 0.02 BAC or greater and no later than 30-minutes after the initial test result. This paragraph of the final rule is estimated to impose no incremental cost and afford no saving because (even though the former rule did not specify a 30-minute time frame for testing), licensees will still incur testing costs, and the instances when a confirmatory test could not be conducted as soon as possible after an initial breath test are very low (delays in testing would most likely only result from equipment malfunctions which are rare).

Paragraph 26.101(b)

This paragraph establishes collection procedures for conducting a confirmatory alcohol test using an EBT as required in final rule provisions in §§ 26.91(b) and (c). This provision will result in one time training costs of breath alcohol collectors which is discussed in this analysis in connection with §§ 26.85(a) and (b).

Paragraph 26.101(c)

This paragraph revises former requirements in Section 2.4(g)(18) in Appendix A to Part 26, which required when necessary, two additional breath specimens be collected from an individual for confirmatory testing. This final paragraph reduces the number of breath specimens collected from two to one unless problems encountered while administering the confirmatory breath test require an additional collection. This final paragraph also prohibits an activity permitted under the former requirements in Section 2.4(g)(18) in Appendix A to Part 26. Specifically, the final paragraph prohibits licensees from calculating an average or otherwise combine results from two or more breath specimens to determine the confirmatory breath alcohol test result. FFD programs will realize minor savings in confirmatory alcohol testing costs resulting from decreasing the duration of the testing process, reducing equipment costs (using fewer exhalent tubes), decreasing worker productivity losses, and reducing collector labor costs.[7] However, the

[7] In order to capture the total costs and savings, the analysis assumes that all savings incurred by offsite collection sites are passed back to licensees (i.e., through lower costs per collection). This assumption depends on the degree to which the offsite collection site industry is price-competitive. To the extent that it is not price competitive, savings will accrue as estimated, but will benefit the offsite collection site rather than licensees (i.e.,

analysis does not calculate any savings because of the infrequency of confirmatory alcohol testing events (less than 2 per reactor per year),[8] and the minor savings (2 minutes and the cost of one exhalent tube per confirmatory - see assumptions in § 26.95).

Paragraph 26.101(d)

This paragraph of the final rule establishes that if an EBT that meets the requirements of §§ 26.91(b) and (c) was used for the initial alcohol test, the same EBT may be used for confirmatory testing. The former requirements in § 26.24(g) required that initial and confirmatory alcohol testing be conducted using different EBTs. Incremental savings associated with this provision are accounted for in the discussion on § 26.91(c).

26.103 Determining a confirmed positive test result for alcohol

This section, including paragraphs (a)–(b), revises former requirements in § 26.24(g) and Section 2.7(f)(2) in Appendix A to Part 26 pertaining to the screening alcohol test result that constitutes a positive test result for a confirmatory alcohol test. The final rule establishes BACs that are more stringent than the former rule's BAC level of 0.04, depending on the length of time an employee has been in work status. Thus, a confirmatory test may yield a positive result with a BAC that is equal to or greater than 0.02 BAC. Each FFD program will incur incremental costs for FFD manager labor to determine the work status for an individual with a confirmatory BAC test result that is equal to or greater than 0.02 and less than 0.04.[9]

The *annual cost per FFD program* is estimated as follows:

$$(NUM_{CPAT} \times PERI_{CPAT}) \times (HOURS_{FFD\ manager} \times WAGE_{FFD\ manager}) \times NUM_{reactors}$$

Parameter	Description
NUM_{CPAT}	Number of confirmed positive breath alcohol test (CPAT) results per reactor per year under former requirements (as discussed in Appendix 2, Exhibit A2-12)
$PERI_{CPAT}$	Percentage increase in the number of confirmed positive alcohol test (CPAT) results under the BACs (as discussed in the assumptions below)
$HOURS_{FFD\ manager}$	Time (per test) for the FFD manager to determine the length of time the employee has been in work status for BACs equal to or greater than 0.02 and less than 0.04 (as discussed in the assumptions below)
$WAGE_{FFD\ manager}$	FFD manager 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:

offsite collection sites will realize savings in labor costs because of the reduced collection time, but will not reduce the cost per collection charged to licensees).

[8]The NRC Information Notice 2003-04 "Summary of Fitness-for-Duty Program Performance Reports for Calendar Year 2000" reported 211 confirmed positive alcohol test results for all licensees.

[9] The incremental costs of other activities resulting from additional confirmed positive alcohol test results attributable to the BAC thresholds are estimated and discussed in connection with paragraph 26.99(b).

- Percentage increase in the number of confirmed positive breath alcohol test (CPAT) results under the BACs: 20 percent.

- Time (per test) for the FFD manager to determine the length of time the employee has been in work status for BACs equal to or greater than 0.02 and less than 0.04: 15 minutes.

26.105 Preparing for urine collection

This section restates former requirements in Section 2.4(g)(5)–(7) in Appendix A to Part 26, which required the collector to instruct donors to remove any unnecessary outer garments, wash their hands, and remain in the presence of the collector until proceeding to the privacy enclosure to provide a urine specimen. This section also adds a new requirement in § 26.105(b) for the collector to evaluate the contents of each donor's pockets of each donor before a specimen donation can commence.

Paragraph 26.105(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(g)(5) in Appendix A to Part 26.

Paragraph 26.105(b)

This paragraph of the final rule adds a new requirement for donors to empty their pockets and display the items to the collector. If the donor refuses to show the collector the contents of their pockets, this action is considered a refusal to test. If the collector identifies an item in a donor's pockets that appears to be a potential adulterant or substitute specimen, the collector must contact the FFD program manager or the MRO for direction as to whether a directly observed collection is warranted. If an item is identified in a donor's pocket which the collector determines to be inadvertently brought to the collection site, the collector is to secure the item and continue with a normal collection process. The number of instances in which a donor may attempt to conceal a potential adulterant or substitute specimen in their pocket is deemed low (due to the donor's knowledge of the inspection process) as is the likelihood of a donor refusing to display the contents of his/her pockets (given the consequences of their action). Incremental costs will result from additional time per collection to empty and inspect the contents of a donor's pockets. Each FFD program will incur a per specimen collection cost of additional lost worker productivity and additional collector labor.

The *annual cost per FFD program* is estimated as follows:

$$NUM_{collections} \times HOURS_{inspection} \times (WAGE_{worker} + WAGE_{collector}) \times NUM_{reactors}$$

Parameter	Description
$NUM_{collections}$	Number of urine collections per reactor per year (as discussed in the assumptions below

Parameter	Description
	and in Appendix 2, Exhibit A2-12)
$HOURS_{inspection}$	Time per collection to empty and inspect contents of a donor's pockets (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$WAGE_{collector}$	Collection site personnel 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:

- Number of urine collections per reactor per year is assumed to be equal to the number of drug tests per reactor per year.

- Time per specimen collection for a donor to empty and the collector to evaluate the contents of a donor's pockets: 2 minutes.

Paragraphs 26.105(c) - (d)

These paragraphs of the final rule impose no incremental cost and afford no saving because they restate former requirements in Section 2.4(g)(6) - (7) in Appendix A to Part 26.

Paragraph 26.105(e)

This paragraph of the final rule establishes collection site procedures for the collector/donor to select and unwrap collection kit materials. This final paragraph imposes no incremental cost and affords no saving because this collection procedure will not increase the time of a specimen collection. The same activity of selecting and unwrapping the collection materials will still occur, but the donor rather than the collector may conduct the activity.

26.107 Collecting a urine specimen

This section restates and clarifies former requirements in Section 2.4 in Appendix A to Part 26, which addressed collector responsibilities during the urine collection process. This section also adds several new requirements, as indicated in the paragraph discussions below.

Paragraph 26.107(a)

This paragraph of the final rule restates a former requirement in Section 2.4(g)(8) in Appendix A to Part 26. This final paragraph also adds a provision which provides the urine collector with discretion as to setting "a reasonable time limit for voiding" by the donor. No significant incremental cost or saving will result from the revision because on average, it is uncommon for donors to take long periods of time to provide specimens.

Paragraph 26.107(b)

This paragraph of the final rule clarifies the former requirements in Sections 2.4(g)(9) and (g)(25) in Appendix A to Part 26 which required the collector to consult with a "higher level supervisor in the drug testing program to review and concur that a collection under direct observation should proceed." This final paragraph clarifies that the collector must contact "FFD program management" to receive direction as to whether an observed collection is warranted in cases where a donor attempts to subvert the collection process (e.g., bringing in a substituted urine specimen or adulterant). No incremental cost or saving will result from this provision as it only clarifies who the collector is to contact regarding a direct observation. In addition, this final paragraph directs the collector to document on the custody and control form a description of the donor's actions that the collector believed demonstrated an attempt by the donor to subvert the testing process. This collector requirement to document the reason for believing a donor has attempted to subvert the testing process offers an employee protection from unwarranted observed collections as the collector must justify the reason that an observed collection is needed. Because the collector's action of documenting a description of the donor's actions on the custody and control form will be very rare, no significant cost or saving will be incurred.

Paragraph 26.107(c)

This paragraph of the final rule restates a former requirement in Section 2.4(g)(12) in Appendix A to Part 26. This final paragraph also adds a new requirement for the collector to inspect the toilet bowl and privacy area used by a donor for a specimen collection for evidence of a subversion attempt. No significant incremental cost or saving will result from the provision because this action is both consistent with current collection site practices, and because inspecting a privacy enclosure takes only a matter of seconds per collection.

26.109 Urine specimen quantity

Paragraph 26.109(a)

This paragraph of the final rule revises the former requirement in Section 2.4(g)(11) in Appendix A to Part 26, under which the minimum quantity of urine to be collected for a drug test was 60 mL. The final rule introduces the term, "predetermined quantity" of urine to describe that a donor must provide a specific quantity of urine based on the licensee's or other entity's testing program. The new provision reduces the minimum quantity of urine to be collected from a donor from 60 mL to 30 mL. That is, at a minimum, the donor must provide 30 mL of urine to permit an HHS-certified laboratory to conduct initial (and confirmatory, when necessary) validity and drug tests as required by 10 CFR Part 26. An additional 15 mL of urine is permitted to be collected for split specimen collections. The final rule also permits licensee and other entity testing programs to collect additional quantities of urine as part of the predetermined quantity based on their own additional specific testing and collection procedures. No incremental change is estimated for the added flexibility in permitting licensees to conduct additional testing beyond the rule requirements in 10 CFR Part 26, as that is allowed as an accommodation to licensees. The reduction in the minimum quantity of urine required (from 60 mL to 30 mL) will reduce the number of instances in which a donor cannot provide the minimum specimen quantity on a first

attempt. Therefore, FFD programs will recognize incremental savings attributable to a reduction in lost worker productivity and reduced collector labor resulting from fewer shy bladder instances.[10]

The *annual saving per FFD program* is estimated as follows:

$$(NUM_{collections} \times PER_{low\ quantity} \times PERD_{low\ quantity}) \times (HOURS_{saved} \times (WAGE_{worker} + WAGE_{collector})) \times NUM_{reactors}$$

Parameter	Description
$NUM_{collections}$	Number of urine collections per reactor per year (as discussed in Appendix 2, Exhibit A2-12)
$PER_{low\ quantity}$	Percentage of collections that are of inadequate quantity after the initial attempt to provide a specimen under the former requirements (as discussed in the assumptions below)
$PERD_{low\ quantity}$	Percentage decrease in the number of shy bladder tests per year that produce inadequate specimens resulting from the reduction in the minimum specimen quantity (from 60 mL to 30 mL) (as discussed in the assumptions below)
$HOURS_{saved}$	Average time per test saved because a donor can provide a sufficient specimen under the final rule (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$WAGE_{collector}$	Collection site personnel 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:

- Number of urine collections per reactor per year is assumed to be equal to the number of drug tests per reactor per year.

- Percentage of collections (per year) that are of inadequate quantity after the initial attempt to provide a specimen under the former requirements : 6.7 percent.[11]

- Percentage decrease in the number of shy bladder tests per year that produce inadequate specimens: 25 percent.

[10] In order to capture the total costs and savings, this analysis assumes that savings incurred by offsite collection sites are passed back to licensees (i.e., lower costs per specimen collection). The validity of this assumption depends on the degree to which the offsite collection site industry is price-competitive. To the extent that it is not price-competitive, savings will accrue as estimated, but will benefit the offsite collection site rather than licensees (i.e., offsite collection sites will realize savings in labor costs because of the reduced collection time, but will not reduce the cost per collection charged to licensees).

[11] Landers, Peter. April 22, 2003. "Looking for Relief, Shy bladder syndrome is widespread. But in many cases it can be treated successfully." Special Report: Personal Health Quarterly 2003-2, The Wall Street Journal. The article cites a 1994 study indicating that 6.7 percent of Americans suffer from shy-bladder syndrome, or what is called paruresis.

- Average time per test saved because a donor can provide a sufficient specimen under the final rule: 1.5 hours.

Paragraph 26.109(b)

This paragraph of the final rule [including subparagraphs (b)(1)–(4)] revises former requirements in Section 2.4(g)(11) in Appendix A to Part 26, which described the collection procedures in the event that a donor provides less than the minimum quantity of urine needed to complete a specimen collection during his or her initial attempt. The incremental costs and savings for this final paragraph are discussed in connection with subparagraphs (b)(1)–(4).

Subparagraph 26.109(b)(1)

This subparagraph revises a former requirement in Section 2.4(g)(11) in Appendix A to Part 26, which permitted a donor to be provided with "a reasonable amount of liquid to drink for this purpose (e.g., a glass of water)" if they cannot provide a urine specimen that meets the minimum quantity requirement during their initial attempt. The revision directs the collector to encourage the donor to drink up to a specific amount of fluid (i.e., 40 ounces) over a three-hour time period. The former rule contained no such maximum restriction on fluid consumption. This analysis assumes that no incremental cost or saving will result from this revised subparagraph because the activity (of providing fluids to the donor) is common to both the former and final rules.

Subparagraph 26.109(b)(2)

This subparagraph adds three new requirements. First, this subparagraph prohibits a licensee or other entity from requiring a donor to provide additional urine specimens to try to meet the licensee's or other entity's predetermined quantity if the donor's initial specimen is at least 30 mL, but less than the predetermined quantity (greater than 30 mL). That is, a donor cannot be compelled to make additional attempts to provide a specimen that meets the licensees's or other entity's predetermined quantity, after the donor has successfully provided an initial specimen of at least 30 mL. Second, this subparagraph prohibits any sanctions from being imposed on a donor who provides a specimen of at least 30 mL but less than the predetermined quantity. Third, this subparagraph requires that a specimen of 30 mL but less than the predetermined quantity be forwarded directly to the an HHS-certified laboratory for testing. The three new requirements in this subparagraph will not result in any incremental costs or savings for FFD programs that send all urine specimens to HHS-certified laboratories. However, the provisions will result in incremental costs for FFD programs with onsite licensee testing facilities because specimens meeting the minimum 30 mL quantity (but less than the predetermined quantity) cannot be tested at the licensee testing facility and must be forwarded directly to an HHS-certified laboratory for testing.

The *annual incremental costs per FFD program with onsite testing facilities* are estimated as follows:

$$(NUM_{drug\ tests} \times PER_{not\ predetermined\ quantity}) \times (COST_{test\ at\ HHS\ lab} - COST_{test\ at\ licensee\ lab}) \times NUM_{reactors}$$

Parameter	Description
$NUM_{drug\ tests}$	Number of drug tests per reactor per year (as discussed in Appendix 2, Exhibit A2-12)
$PER_{not\ predetermined\ quantity}$	Percentage of urine specimens at least 30 mL in volume, but less than the licensee's or other entity's predetermined quantity of urine (as discussed in the assumptions below)
$COST_{test\ at\ HHS\ lab}$	Cost to conduct initial drug testing and initial validity testing on a urine specimen at an HHS-certified laboratory for FFD programs that primarily use onsite testing facilities (as discussed in Appendix 2, Exhibit A2-13)
$COST_{test\ at\ licensee\ lab}$	Cost to conduct initial drug testing and initial validity testing on a urine specimen at an onsite licensee testing facility (as discussed in the assumptions below and in Appendix 2, Exhibit A2-13)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- FFD programs that conduct initial drug testing at onsite testing facilities send fewer specimens to HHS-certified laboratories than do FFD programs that do not operate onsite testing facilities, and so must pay a higher per specimen cost for drug and validity testing (both initial and confirmatory, when necessary).

- Percentage of urine specimens of at least 30 mL in volume, but less than the licensee or other entity's predetermined quantity: 1 percent.

Subparagraph 26.109(b)(3)

The paragraph revises former requirements in Section 2.4(g)(11) in Appendix A to Part 26. In situations where a donor has not provided a urine specimen of adequate volume (at least 30 mL) within 3 hours of the initial unsuccessful attempt, this revised subparagraph instructs the collector to terminate the testing process and notify the FFD manager or MRO to initiate the shy bladder procedures in § 26.119. The former rule only required that the collector contact the appropriate authority to obtain guidance on the action to be taken. The final paragraph provides a specific requirement for the collector to notify the FFD manager or MRO to initial shy bladder procedures. This final subparagraph will not result in any incremental costs or savings because the collector must still contact an individual to initiate additional actions related to the shy bladder situation.

Subparagraph 26.109(b)(4)

This subparagraph revises the former requirement in Section 2.4(g)(11) in Appendix A to Part 26, to prohibit, rather than require, the pooling of successive urine specimens. Donors must now provide a minimum of 30 mL of urine in a single specimen collection attempt. The final rule also requires that urine collectors must discard specimens of less than 30 mL. If the collector has

a reason to believe that a donor has diluted, adulterated, substituted, or tampered with their specimen of 15 mL or more but less than 30 mL, the specimen must be sent to an HHS-certified laboratory for testing. Although FFD programs may realize an additional cost to send specimens to an HHS-certified laboratory that are 15 mL or more but less than 30 mL and collected from a donor who is suspected of diluting, adulterating, substituting, or tampering with their specimen, the analysis assumes that no incremental costs or savings will result because of the infrequency of these situations.

26.111 Checking the acceptability of the urine specimen

Paragraph 26.111(a)

This paragraph of the final rule revises former requirements in Section 2.4(g)(13) in Appendix A to Part 26, which required collectors to measure the temperature of a urine specimen within 4 minutes of receiving the specimen from the donor. This paragraph of the final rule revises the former rule's urine specimen temperature requirements in Section 2.4(g)(14) in Appendix A to Part 26. Specifically, the final rule expands the acceptable urine specimen temperature range from (90.5°F – 99.8°F) to (90°F – 100°F). Any specimen outside the (90°F – 100°F) temperature range indicates that a donor may have attempted to subvert the testing process. The analysis does not estimate any saving from this revision because the change in the temperature range is minor.

Paragraph 26.111(b)

This paragraph of the final rule revises former requirements in Section 2.4(g)(15) in Appendix A to Part 26, which specified that "immediately after a urine specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted in the permanent record book." This final paragraph requires that immediately after a urine specimen is collected, "the collector shall also inspect the specimen to determine its color and clarity and look for any signs of contaminants or adulteration. Any unusual findings must be noted on the custody-and-control form." This final paragraph changes the required location that the information is to be recorded from a permanent recordbook to the custody-and-control form. This final paragraph imposes no incremental cost and affords no saving because the collector must still inspect each specimen and document any unusual findings (even if in a different place).

Paragraph 26.111(c)

This paragraph of the final rule revises former requirements in Sections 2.4(g)(17) and 2.4(g)(25) in Appendix A to Part 26, which instructed the urine collector, after receiving approval from a "higher level supervisor in the drug testing program," to perform a second collection as soon as possible under direct observation "whenever there is a reason to believe that a particular individual may alter or substitute the urine specimen." The final paragraph specifies that the collector should contact the designated FFD program manager if there is reason to believe the individual may have diluted, substituted, or adulterated the specimen based upon temperature or other observations. It also permits the FFD manager to consult with the MRO to determine

whether a subversion attempt has occurred. There are no incremental costs or savings attributable to these clarifications because this analysis assumes that these requirements are consistent with existing practices.

Paragraph 26.111(d)

This paragraph of the final rule revises former Section 2.4(g)(16) in Appendix A to Part 26, which required all urine specimens suspected of being adulterated or diluted to be "forwarded to the laboratory for testing." This revised paragraph specifies that a specimen of sufficient quantity (at least 15 mL) that is suspected of having been diluted, substituted, or adulterated and any specimen of 15 mL or more that has been collected under direct observation in accordance with paragraph (c) of this section, must be "sent directly to the HHS-certified laboratory for testing." The only minor incremental costs or savings that may result from the requirement pertain to FFD programs with onsite licensee testing facilities, because FFD programs that send all specimens offsite for testing at an HHS-certified laboratory already comply with this requirement. The analysis assumes, however, that even FFD programs with onsite testing facilities already send any suspect urine specimens directly to an HHS-certified laboratory because HHS-certified laboratories have more sophisticated equipment to identify potential specimen validity concerns.

Paragraph 26.111(e)

This paragraph of the final rule revises former Section 2.4(g)(16) in Appendix A to Part 26, which required all urine specimens suspected of being adulterated or diluted to be forwarded to an HHS-certified laboratory. This final paragraph specifies that the collector must also preserve a suspect urine specimen for possible testing. This paragraph of the final rule imposes no incremental cost and affords no saving because it is consistent with existing collection site practices.

Paragraph 26.111(f)

This paragraph of the final rule defines the specific criteria to be used by a collector to determine whether a urine specimen is acceptable (i.e., is free of apparent contaminants, meets the required quantity of at least 30 mL, and is within acceptable temperature range). This analysis assumes no incremental costs or savings are attributable to this final paragraph because collectors currently use these criteria to determine whether a urine specimen is acceptable, although the minimum quantity of urine has been reduced from 60 mL to 30 mL, as discussed in connection with § 26.109.

26.113 Splitting the urine specimen

This section of the final rule [including paragraphs (a)–(c)] imposes no incremental costs and affords no savings because it clarifies the former requirements in Sections 2.4(g)(20) and 2.7(j) in Appendix A to Part 26, which detailed the procedures for collecting split specimens. Paragraph 26.113(b) revises the former requirement in Section 2.7(j) which instructed the urine

collector to pour one half of the urine specimen into each specimen bottle. Paragraph 26.113(b) instructs the collector, to pour 30 mL of urine into Bottle A and a minimum of 15 mL into Bottle B. The final paragraph also requires that if there is less than 15 mL of urine available for Bottle B, then the collector must pour the remaining urine into Bottle B and forward the specimens in Bottles A and B to the HHS-certified laboratory for drug and validity testing. The quantities apportioned to each split specimen bottle have been revised, but no cost or saving will result from this modified procedure.

26.115 Collecting a urine specimen under direct observation

Paragraph 26.115(a)

This paragraph of the final rule restates without substantive change former requirements in Section 2.4(f)(1)-(3) in Appendix A to Part 26 which specified the criteria indicating exclusive grounds that a donor has attempted to alter or substitute their urine specimen.

Paragraph 26.115(b)

This paragraph establishes a new requirement that in instances where an observed collection is deemed warranted by the collector, the collector must obtain agreement of the FFD manager or MRO to obtain a specimen under direct observation. No incremental cost or savings will result from this final paragraph because situations where an observed collection is warranted are rare.

Paragraphs 26.115(c)

The paragraph of the final rule adds a requirement that the collector inform the donor of the reason(s) for the directly observed collection so that the donor is aware of the nature of the concern that has initiated a directly observed collection. No costs or savings will result from this final paragraph because situations where an observed collection is warranted are rare.

Paragraph 26.115(d)

The paragraph of the final rule establishes new recordkeeping requirements related to the directly observed collection. The final paragraph requires the collector to record on the specimen's custody-and-control form that the specimen was collected under direct observation and the reason for the directly observed collection. The requirement is necessary to ensure that the HHS-certified laboratory and the MRO have this information available when the specimen is tested and the MRO conducts his or her review of the test results, as is required under § 26.185. No costs or savings will result from this final paragraph because situations where an observed collection is warranted are rare.

Paragraph 26.115(e)

This paragraph of the final rule retains and combines the former requirements in Sections 1.2, 2.4(b), 2.4(g)(14), (g)(17), and (g)(25) in Appendix A to Part 26, which required that the

individual who observes the specimen collection must be of the same gender as the donor. Consistent with the former requirements, the final rule permits another individual of the same gender to serve as the observer if a qualified urine collector of the same gender is not available, as long as the observer receives the instructions specified in § 26.115(f).

Paragraph 26.115(f)

This paragraph of the final rule adds new requirements for conducting directly observed collections. These more detailed procedures are necessary because devices and techniques to subvert the testing process have been developed since Part 26 was first published that can be used under direct observation without detection. Therefore, the changes have been made to increase the likelihood of detecting such attempts to subvert the testing process and, thereby, increase the effectiveness of directly observed collections in assuring that a valid specimen is obtained from the donor. No costs or savings will result from this final paragraph because situations where an observed collection is warranted are rare.

Paragraph 26.115(g)

This paragraph of the final rule has been added to clarify that a donor's refusal to participate in the directly observed collection constitutes an act to subvert the testing process, under § 26.75(b). Former Section 2.4(j) in Appendix A to Part 26 required the collector to inform the MRO, and the MRO to inform licensee management, if a donor fails to cooperate with the specimen collection process, including, but not limited, to a refusal to provide a complete specimen, complete paperwork, or initial the specimen bottles. The former requirement did not specifically mention that a refusal to participate in a directly observed collection is also an instance of a failure to cooperate. In addition, the former rule did not require the licensee or other entity to impose sanctions on a donor for refusing to be tested. No costs or savings will result from this final paragraph because situations where an observed collection is warranted are rare.

Paragraph 26.115(h)

This paragraph of the final rule adds new collection requirements for collectors to follow if a directly observed collection was required, but was not performed. The collector would inform the FFD program manager or designee of the omission, who would ensure that a directly observed collection is immediately performed. No costs or savings will result from this final paragraph because situations where an observed collection is warranted are rare.

26.117 Preparing urine specimens for storage and shipping

Paragraph 26.117(a)

This paragraph of the final rule restates without substantive change former requirements in Section 2.4(g)(20) in Appendix A to Part 26, which pertained to the collector keeping the urine specimen in view of the donor at all times before sealing and labeling the specimen. This

paragraph of the final rule imposes no incremental cost and affords no saving because it is consistent with existing licensee collection practices.

Paragraph 26.117(b)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(g)(21) in Appendix A to Part 26.

Paragraph 26.117(c)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(g)(22) in Appendix A to Part 26.

Paragraph 26.117(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(g)(23) in Appendix A to Part 26.

Paragraph 26.117(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive changes the former requirements in Section 2.4(g)(26) in Appendix A to Part 26.

Paragraph 26.117(f)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(g)(27) in Appendix A to Part 26.

Paragraph 26.117(g)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(g)(28) in Appendix A to Part 26.

Paragraph 26.117(h)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(c)(2) in Appendix A to Part 26.

Paragraph 26.117(i)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive changes former requirements in Section 2.4(i) in Appendix A to Part 26 which pertain to specimen packaging procedures.

Paragraph 26.117(j)

This paragraph of the final rule clarifies and revises former requirements (primarily in Section 2.7(c) in Appendix A to Part 26) regarding 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 achieve the performance standard by implementing the more specific criteria from the former rule, which are also restated in the final rule. The final paragraph also relaxes refrigeration criteria for most specimens, but tightens them for specimens that are suspected of having been substituted, adulterated, or tampered with. Finally, the final paragraph adds a requirement that the collection site must send specimens to a licensee testing facility or HHS-certified laboratory as soon as reasonably practical, with a time limit of 2 business days from the shipping of a specimen to the receipt of the specimen at the appropriate laboratory, except under unusual circumstances. It is believed that the new provisions in this final paragraph are consistent with current industry practices. To the extent (if any) that the new refrigeration standards (some relaxed, some tightened) might require licensees to change their operating practices, the net effect is likely to be small. As a result of these uncertainties (including a lack of data) and the likelihood that any impact would be small, this analysis does not quantify costs or savings resulting from the final paragraph.

Paragraph 26.117(k)

This paragraph of the final rule clarifies former requirements in Section 2.4(h) in Appendix A to Part 26, stating that the date and purpose be documented on the chain-of-custody form for a specimen each time the specimen is handled or transferred, and every individual in the chain of custody shall be identified. This final paragraph clarifies that because couriers, express carriers, and postal service personnel do not have access to the custody-and-control forms, these individuals are not required to document chain of custody during transit of a urine specimen. However, this final 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. This paragraph of the final rule imposes no incremental cost and affords no saving because it describes existing courier, express carrier, and postal service shipment tracking practices.

26.119 Determining "shy" bladder

This section of the final rule replaces former requirements in Section 2.4(g)(11) in Appendix A to Part 26, which required that the collection site must contact the appropriate authority to obtain guidance on the action to be taken when a donor cannot provide an adequate volume of urine. This final paragraph adopts "shy bladder procedures" consistent with U.S. DOT regulations (49 CFR 40.193). All costs are considered incremental because this is a new requirement. Specific incremental costs include labor (or productivity losses) associated with the donor, the FFD manager, the MRO, and a licensed physician, and are described in the paragraph discussions below.

The equation presented at the end of this section calculates the incremental costs combined for all seven paragraphs within § 26.119, as follows:

- Paragraph 26.119(a) establishes a new requirement for the FFD program personnel to direct the donor to obtain a medical evaluation from a licensed physician within 5 business days of a donor's inability to provide an adequate urine specimen of at least 30 mL. The MRO must approve the physician to conduct the evaluation (an MRO can perform the evaluation if he or she possesses appropriate expertise). Incremental costs per FFD program consist of lost worker productivity while obtaining the medical evaluation, MRO labor to evaluate and agree with the selection of physician, and the cost of the medical evaluation.

- Paragraphs 26.119(b), (c), and (d) establish new requirements necessitating that the MRO provide the physician selected to perform a medical evaluation with the physical and psychological conditions that constitute a medical condition that could preclude a donor from providing an adequate quantity of urine. The MRO must also instruct the physician to provide a written statement of the conclusions of the evaluation to the MRO. The incremental costs include MRO labor to communicate the specific evaluation requirements to the examining physician.

- Paragraphs 26.119(e) and (f) require the physician evaluating the donor to provide a written statement to the MRO regarding the findings and conclusions from his or her evaluation. The report must state whether a medical condition exists that precludes the donor from providing sufficient specimens in future collections. The incremental cost consists of the cost of obtaining the physician's written statement.

- Paragraph 26.119(g) describes the required MRO findings, which are to be based on results of the physician's evaluation of the donor. Incremental costs consist of MRO labor to review the physician evaluation, make a determination on the donor's condition, and communicate the results.

The annual cost per FFD program associated with section 26.119 is estimated as follows:

$$NUM_{shy\ bladder} \times [COST_{medical\ evaluation} + ((HOURS_{medical\ evaluation} \times WAGE_{worker}) + (HOURS_{FFD\ manager} \times WAGE_{FFD\ manager}) + (HOURS_{MRO} \times WAGE_{MRO}))] \times NUM_{facilities}$$

Parameter	**Description**
$NUM_{shy\ bladder}$	Number of urine collections unable to be completed because of inadequate specimen volume after 3 hours, per facility per year (as discussed in the assumptions below)
$COST_{medical\ evalutaion}$	Cost of a medical evaluation and written report from a licensed physician per incident where an employee is unable to provide the minimum quantity of urine after 3 hours (as discussed in the assumptions below)
$HOURS_{medical\ evaluation}$	Time per medical evaluation (including travel to and from the physician's office) (as discussed in the assumptions below)

Parameter	Description
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$HOURS_{FFD\ manager}$	Time for an FFD manager per incident where an employee is unable to provide the minimum quantity of urine after 3 hours (as discussed in the assumptions below)
$WAGE_{FFD\ manager}$	FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11)
$HOURS_{MRO}$	MRO time per incident where a donor is unable to provide the minimum quantity of urine after 3 hours to select a physician, instruct the physician on the medical evaluation that must be conducted, and review and communicate the medical evaluation results to the FFD manager and worker (as discussed in the assumptions below)
$WAGE_{MRO}$	MRO wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{facilities}$	Number of facilities per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of urine collections unable to be completed because of inadequate specimen volume after 3 hours, per facility per year: 1.

- Cost of a medical evaluation and written report from a physician per incident where a donor is unable to provide the minimum quantity of urine after 3 hours: $300.00.

- Time per medical evaluation (including travel to and from the physician's office): 1.5 hours.

- Time for an FFD program manager per incident where an employee is unable to provide the minimum quantity of urine after 3 hours to direct an employee to proceed to a physician for a medical evaluation, to consult with the MRO regarding an appropriate physician to conduct a shy bladder examination, and to perform administrative activities associated with the MRO's results: 2 hours.

- MRO time per incident where an employee is unable to provide the minimum quantity of urine after 3 hours to select a physician, instruct the physician on the medical evaluation that must be conducted, and communicate the medical evaluation results to the FFD manager and worker: 2 hours.