

## **Subpart B: Program Elements**

### **26.21 Fitness-for-Duty Program**

This section of the final rule imposes no incremental cost and affords no saving because it merely states that licensees and other entities specified in paragraph 26.3(a) through (c) must implement FFD programs that comply with this part, as required by paragraph 26.3(b) of the former rule.

### **26.23 Performance Objectives**

#### **Paragraphs 26.23(a)–(d)**

Paragraphs 26.23(a)-(c) of the final rule merely clarify the program performance objectives contained in paragraphs 26.10(a)-(b) of the former rule. Paragraph 26.23(d) of the final rule amends and clarifies former paragraph 26.10(c) regarding the objective that FFD programs provide reasonable assurance that workplaces specified in § 26.3(a), (b), and, if applicable, (c) are free from the presence and effects of illegal drugs and alcohol. The analysis assumes that any incremental costs and savings related to this objective are imposed by subsequent provisions that implement this objective.

#### **Paragraph 26.23(e)**

This paragraph of the final rule amends the performance objectives for FFD programs to include reasonable assurance that the effects of fatigue and degraded alertness are managed commensurate with maintaining public health and safety. Incremental costs associated with this performance objective are analyzed under the relevant sections that implement the objective, particularly the provisions in Subpart I.

### **26.25 Reserved**

### **26.27 Written Policy and Procedures**

#### **Paragraph 26.27(a)**

This paragraph amends requirements, in § 26.20 of the former rule, regarding the establishment, implementation, and maintenance of written policies and procedures designed to meet the general performance objectives and requirements of this part. Licensees and other entities must revise their existing policies, procedures, and contracts with labs or other C/Vs according to paragraphs 26.27(b) and (c), resulting in incremental costs. The costs of the revisions will include policy and procedure development and revision, legal support, and clerical support. Costs associated with revisions to the FFD training program are calculated separately in connection with paragraph 26.29(a).

The *one-time cost per program* results from the sum of the following costs:

- One-time cost per program to account for FFD manager and clerical personnel time and to contract a legal consultant is calculated as follows:

$$(HOURS_{Manager} \times WAGE_{Manager}) + (HOURS_{Legal} \times WAGE_{Legal}) + (HOURS_{Clerical} \times WAGE_{Clerical})$$

- One-time cost per program to account for facility supervisor time to implement the corporate policies at the facility level is calculated as follows:

$$HOURS_{Facility\ Supervisor} \times WAGE_{Facility\ Supervisor} \times NUM_{Facilities}$$

Parameter	Description
HOURS <sub>Clerical</sub>	Hours of clerical personnel to support revision of policies, procedures, and contracts per program (as described in assumptions below)
HOURS <sub>Facility Supervisor</sub>	Hours of facility supervisor time to implement revised corporate policies and procedures per facility (as described in assumptions below)
HOURS <sub>Legal</sub>	Hours of legal assistance to review and revise policies, procedures, and contracts per program (as described in assumptions below)
HOURS <sub>Manager</sub>	Hours of FFD program manager labor to develop and revise policies, procedures, and contracts per program (as described in assumptions below)
NUM <sub>Facilities</sub>	Number of facilities (as described in Appendix 2, Exhibit A2-14)
WAGE <sub>Clerical</sub>	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Facility Supervisor</sub>	Facility supervisor wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Legal</sub>	Legal consultant wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Manager</sub>	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Hours of FFD program manager labor to develop and revise policies, procedures, and contracts per program: 370 hours.
- Hours of legal assistance to review and revise policies, procedures, and contracts per program: 95 hours.
- Hours of clerical personnel to support revision of policies, procedures, and contracts per program: 95 hours.
- Hours of facility supervisor time to implement revised corporate policies and procedures: 40 hours.
- Policy and procedure revisions are developed once per operating firm, regardless of the number of sites or facilities the firm operates.

## **Paragraph 26.27(b)**

This paragraph of the final rule establishes regulatory requirements regarding the content of policy statements. The final paragraph requires that written policies and procedures be clear, concise and readily available to all individuals subject to the policy such that they may understand what is expected of them and what consequences may result from lack of adherence to the policy. These requirements amend the requirements contained in § 26.20 of the former rule. The analysis calculates the cost of this revision as part of the related revisions required under paragraph 26.27(a) except as discussed below.

### ***Subparagraphs 26.27(b)(1)–26.27(b)(10)***

These subparagraphs of the final rule establish regulatory requirements regarding the content of policy statements. These subparagraphs of the final rule highlight the minimum content of the written policies and procedures available to individuals subject to the policy. These subparagraphs provide more detail on what to include in the written policies and procedures than is contained in paragraph 26.20(a) of the former rule. The analysis calculates the cost of this revision as part of the related revisions required under paragraph 26.27(a).

### ***Subparagraph 26.27(b)(11)***

This paragraph requires licensees' written policies and procedures to describe the responsibility of individuals subject to the FFD program (i.e., other than the supervisors, managers, and escorts who are addressed in 26.27(b)(10)) to report FFD concerns (e.g., concerns identified as a result of behavioral observation). The cost of revising the policies and procedures to include this description is included in the calculation under 26.27(a). The new policy will be communicated to employees through the training program required under 26.29 (the costs of which are calculated under 26.29). As a result of the new policy, there will be an increase in the number of for-cause referrals, the number of drug and alcohol tests performed, and the number of positive test results that must undergo confirmatory testing. The analysis calculates the cost of these activities under paragraph 26.33.

## **Paragraph 26.27(c)**

### ***Subparagraph 26.27(c)(1)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it only describes the written procedures that must be prepared, implemented, and maintained by licensees and other entities related to testing for drugs and alcohol. The requirement to address these procedures is already contained in paragraph 26.20(c) of the former rule.

### ***Subparagraph 26.27(c)(2)(i) and (ii)***

These subparagraphs of the final rule impose no incremental cost and afford no saving because

they merely state that licensee and other entity written policies and procedures must describe the immediate and follow-up actions to be taken and procedures to be followed when an individual has been involved in the use, sale, or possession of illegal drugs and when an individual has consumed any alcohol during the abstinence period, while on duty, or to excess before reporting to duty. These requirements are already contained in paragraph 26.20(d) of the former rule.

***Subparagraph 26.27(c)(2)(iii)–(v)***

These subparagraphs of the final rule impose no incremental cost and afford no saving because they merely state that licensee and other entity written policies and procedures must describe the follow-up actions to be taken and procedures to be followed when an individual has attempted to subvert the testing process, refused to provide a specimen for analysis, and had legal action taken on a drug or alcohol related charge. The costs associated with revising licensee and other entity written policy and procedures to address these violations of FFD policy are addressed in paragraph 26.27(a).

***Subparagraph 26.27(c)(3)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it only requires that licensee and other entity written policies and procedures must describe (1) the process to ensure that persons called in to perform an unscheduled working tour are fit for duty, and (2) the requirements for licensee and other entity personnel who are scheduled by licensee emergency plans and procedures to physically report to a licensee’s Technical Support Center or Emergency Operations Facility. The former rule already required these descriptions to be contained in licensee written policies and procedures under former subparagraph 26.20(e).

***Subparagraph 26.27(c)(4)***

This subparagraph of the final rule requires that licensee and other entity written policies and procedures must describe the process to be followed if an individual’s behavior indicates a potential FFD concern. Although licensees have indicated that the written procedure for managers, supervisors, and escorts to report FFD concerns is well established, the final rule, in conjunction with 26.27(b)(11), adds provisions that all employees are required to report FFD concerns. As a result, the procedures may need to be revised. The incremental cost of these revisions are included in the complete written policy revision calculated under 26.27(a) of this analysis, and the cost of implementing the policy and process is calculated under 26.33.

**Paragraph 26.27(d)**

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely retains requirements contained in paragraph 26.20(f) of the former rule stating that the NRC may review licensee or other entity written policies and procedures at any time to assure that the performance objectives of this part are met.

**26.29 Training**

**Paragraph 26.29(a)**

This paragraph requires licensees to revise their training programs and training materials to account for the new FFD provisions in the final rule and to include behavioral observation training for all individuals subject to this Subpart. (Currently, behavioral observation is included only in supervisory-level training.) Licensees will incur costs to revise their training programs and materials to reflect the new regulatory provisions. However, the provision to include behavioral observation training for all individuals subject to the rule is already in effect due to the AAO. Therefore, there will be no incremental costs associated with the behavioral observation training provision, except under the alternative Pre-Order Baseline.

The *one-time cost per program* associated with revising the training program and training materials to account for new FFD provisions in the final rule are calculated as follows:

$$(HOURS_{Trainer} \times WAGE_{Trainer}) + (HOURS_{Training\_Manager} \times WAGE_{Training\_Manager}) + (HOURS_{Manager} \times WAGE_{Manager}) + (HOURS_{Clerical} \times WAGE_{Clerical})$$

Parameter	Description
HOURS <sub>Manager</sub>	One-time hours of FFD program manager time per program to review the revised training program and revised training materials to account for new FFD provisions in the final rule (described in assumptions below)
HOURS <sub>Trainer</sub>	One-time hours of trainer time per program to revise the training program and training materials to account for new FFD provisions in the final rule (described in assumptions below)
HOURS <sub>Training_Manager</sub>	One-time hours of training manager time per program to review the revised training program and revised training materials to account for new FFD provisions in the final rule (described in assumptions below)
HOURS <sub>Clerical</sub>	One-time hours of clerical personnel per program to support the revision of the training program and training materials to account for new FFD provisions in the final rule (described in assumptions below)
WAGE <sub>Trainer</sub>	Trainer wage rate (described in Appendix 2, Exhibit A2-11)
WAGE <sub>Training_Manager</sub>	Training manager wage rate (described in Appendix 2, Exhibit A2-11)
WAGE <sub>Manager</sub>	FFD program manager wage rate (described in Appendix 2, Exhibit A2-11)
WAGE <sub>Clerical</sub>	Clerical personnel wage rate (described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Hours of trainer time per program to revise the training program and training materials to address new FFD provisions in the final rule: 20 hours.
- Hours of training manager time per program to review the revised training program and revised training materials to address new FFD provisions in the final rule: 2 hours.

- Hours of FFD program manager time per program to review the revised training program and revised training materials to address new FFD provisions in the final rule: 2 hours.
- Hours of clerical personnel to support the revision of the training program and training materials addressing new FFD provisions in the final rule: 4 hours.

*Sensitivity Analysis Note - Pre-Order Baseline*

Relative to the regulations in effect prior to NRC’s issuance of the Access Authorization Order, this final paragraph results in additional incremental costs. The additional costs arise from the requirement to include behavioral observation training for all individuals subject to the rule. (Currently, behavioral observation is included only in supervisory-level training.)

The revisions to the training program and processes related to behavioral observation training will cause licensees to incur incremental costs for the following activities:

- Training course revisions
- Upgrade to supervisory-level training addressing behavioral observation
  - One-time
  - Annual
- Refresher training

*Training Course Revisions.* The incremental changes presented in subparagraph 26.29(a)(9) (as well as the AAO) will require licensees to revise their training programs to incorporate behavioral observation training for all individuals subject to the rule. *The one-time cost per program* associated with revising the training program results from the following:

$$(HOURS_{Trainer} \times WAGE_{Trainer}) + (HOURS_{Training\_Manager} \times WAGE_{Training\_Manager}) + (HOURS_{Manager} \times WAGE_{Manager}) + (HOURS_{Clerical} \times WAGE_{Clerical})$$

<b>Parameter</b>	<b>Description</b>
HOURS <sub>Trainer</sub>	Hours of trainer time per program to make revisions to the training program (as described in assumptions below)
HOURS <sub>Training_Manager</sub>	Hours of training manager time per program to review the revised training program (as described in assumptions below)
HOURS <sub>Clerical</sub>	Hours of clerical personnel per program to support the training program revisions process (as described in assumptions below)
HOURS <sub>Manager</sub>	Hours of FFD program manager time per program to review the revised training program (as described in assumptions below)
WAGE <sub>Trainer</sub>	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Training_Manager</sub>	Training manager wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Clerical</sub>	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Manager</sub>	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Hours of trainer time per program to make revisions to the training program addressing behavioral observation for all individuals subject to the rule: 12 hours.
- Hours of training manager time per program to review revisions to the training program addressing behavioral observation for all individuals subject to the rule: 2 hours.
- Hours of FFD program manager time per program to review revisions to the training program addressing behavioral observation for all individuals subject to the rule: 2 hours.
- Hours of clerical personnel per program to support the training program revisions process: 4 hours.

*Initial Behavioral Observation Training for All Individuals Who Are Subject to the Rule.*

Paragraph 26.29(a) also requires training in behavioral observation for all individuals who are subject to the rule, rather than only for supervisors and escorts as required in § 26.22 of the former rule. In other words, all individuals must receive what currently is supervisory-level training. As a result of this new training requirement, licensees will incur a one-time cost to retrain all existing employees who have not previously received training in behavioral observation, an annual cost to train newly hired employees in behavioral observation and an annual cost to provide behavioral observation refresher training as required under subparagraph 26.29(c)(2).

Licensees will incur a *one-time incremental cost* in order to provide updated training to all individuals who are already covered by the FFD program, but who have not already had full supervisory-level training. The *one-time cost per program* results from the sum of the following costs:<sup>1</sup>

- One-time cost per program for employees not previously trained at the supervisory level to take updated behavioral observation training and a comprehensive examination is calculated as follows:

$$[NUM_{Employees} \times PER_{Non-Supervisory} \times (HOURS_{Training} + HOURS_{Examination}) \times WAGE_{Worker} \times NUM_{Units}] \times PER_{Cost}$$

- One-time cost per program for trainers to administer behavioral observation training to those employees not previously trained at the supervisory level is

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<sup>1</sup> This calculation includes costs associated with administering a comprehensive examination because the entire activity of requiring existing employees to update their training and pass an examination represents an incremental requirement.

calculated as follows:<sup>2</sup>

$$[NUM_{Sessions} \times (HOURS_{Training} + HOURS_{Examination} + HOURS_{Preparation}) \times WAGE_{Trainer} \times NUM_{Units}] \times PER_{Cost}$$

Parameter	Description
HOURS <sub>Examination</sub>	Length of comprehensive examination (as described in assumptions below)
HOURS <sub>Preparation</sub>	Hours of preparation and examination grading per session (as described in assumptions below)
HOURS <sub>Training</sub>	Length of updated supervisory-level training (as described in assumptions below)
NUM <sub>Employees</sub>	Number of employees per unit (as described in Appendix 2, Exhibit A2-14)
NUM <sub>Units</sub>	Number of units per program (as described in Appendix 2, Exhibit A2-14)
NUM <sub>Sessions</sub>	Number of training sessions per unit (as described in assumptions below)
PER <sub>Cost</sub>	Percentage of cost applied to a given unit (as described in assumptions below)
PER <sub>Non-Supervisory</sub>	Percentage of employees trained at the non-supervisory level under the former rule (as described in assumptions below)
WAGE <sub>Trainer</sub>	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Worker</sub>	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Percentage of employees trained at the non-supervisory level under the former rule: 85%.
- Length of updated training, including behavioral observation: 4 hours.
- Length of comprehensive examination: 0.5 hours.
- Number of training sessions assumes 50 workers per session.
- Hours of preparation and examination grading per session: 2 hours.
- Licensees have indicated that 75 percent of facilities already train all employees at this higher supervisory level and, therefore, would not incur any incremental cost under this requirement. Because the analysis cannot identify which facilities are already training at the higher level and which are not, the analysis assumes that each unit will incur the incremental cost of 25 percent of the activity.

*Annual Initial Training.* An incremental cost for annual training for individuals, such as new workers not yet covered under FFD programs or workers updating their authorization, will also lead to increased costs. This is attributable to the longer length of supervisory-level training in

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<sup>2</sup> Although many licensees may be conducting computer-based trainings, the analysis utilizes a class-based format, which may result in an overestimate of the cost of incremental training activities.

relation to training previously conducted under the former rule. The *annual cost per program* results from the sum of the following costs:<sup>3</sup>

- Annual cost per program for incoming employees to take the longer training course addressing behavioral observation is calculated as follows:

$$[NUM_{Applicants} \times PER_{Non-Supervisory} \times (HOURS_{Supervisory} - HOURS_{Non-Supervisory}) \times WAGE_{Worker} \times NUM_{Units}] \times PER_{Cost}$$

- Annual cost per program for trainers to administer the longer behavioral observation training to incoming employees is calculated as follows:<sup>4</sup>

$$[NUM_{Sessions} \times (HOURS_{Supervisory} - HOURS_{Non-Supervisory}) \times WAGE_{Trainer} \times NUM_{Units}] \times PER_{Cost}$$

Parameter	Description
HOURS <sub>Non-Supervisory</sub>	Length of non-supervisory-level training course per applicant (as described in assumptions below)
HOURS <sub>Supervisory</sub>	Length of supervisory-level training course per applicant (as described in assumptions below)
NUM <sub>Applicants</sub>	Annual number of applicants for initial and update authorization per unit (as described in Appendix 2, Exhibit A2-12)
NUM <sub>Units</sub>	Number of units per program (as described in Appendix 2, Exhibit A2-14)
NUM <sub>Sessions</sub>	Annual number of supervisory-level training sessions per unit (as described in assumptions below)
PER <sub>Cost</sub>	Percentage of cost applied to a given facility (as described in assumptions below)
PER <sub>Non-Supervisory</sub>	Percentage of applicants for initial and update authorization trained at the non-supervisory-level under the former rule (as described in assumptions below)
WAGE <sub>Trainer</sub>	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Worker</sub>	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Percentage of applicants for initial and update authorization trained at the non-supervisory level under the former rule: 85%.
- Length of supervisory-level training course per applicant: 4 hours.
- Length of non-supervisory-level training course per applicant: 2 hours.

<sup>3</sup> This calculation does not include the costs associated with administering the comprehensive examination required under paragraph 26.29(b) because new hires are already required to take a comprehensive examination. Therefore, the examination does not represent an incremental requirement.

<sup>4</sup> Although many licensees may be conducting computer-based trainings, the analysis utilizes a class-based format, which may result in an overestimate of the cost of incremental training activities.

- Annual number of supervisory-level training sessions per unit assumes 20 workers per session.
- Licensees have indicated that 75 percent of facilities already train all employees at this higher supervisory level and, therefore, would not incur any incremental cost under this requirement. Because the analysis cannot identify which facilities are already training at the higher level and which are not, the analysis assumes that each unit will incur the incremental cost of 25 percent of the activity.

*Annual Refresher Training.* Licensees will have to conduct refresher training. As a result, licensees will incur an incremental cost for some employees (i.e., those who are currently taking non-supervisory-level refresher training) because of the increased time required to conduct behavioral observation refresher training instead of non-supervisory-level training as required by the former rule. Although providing only one level of training (as opposed to two) may represent a potential savings, the savings are difficult to quantify and may be negligible when considering administrative costs associated with providing an optional comprehensive examination in lieu of refresher training under subparagraph 26.29(c)(2). Despite the provision of this optional comprehensive “challenge” examination, the savings of which are presented separately, some workers will continue to take refresher training. The *annual cost per program* results from the sum of the following costs:

- Annual cost per program for employees to take the longer behavioral observation refresher training is calculated as follows:

$$[NUM_{Employees} \times PER_{Non-Supervisory} \times PER_{Refresher} \times (HOURS_{Supervisory} - HOURS_{Non-Supervisory}) \times WAGE_{Worker} \times NUM_{Units}] \times PER_{Cost}$$

- Annual cost per program for trainers to administer the longer behavioral observation refresher training is calculated as follows:<sup>5</sup>

$$[NUM_{Sessions} \times (HOURS_{Supervisory} - HOURS_{Non-Supervisory}) \times WAGE_{Trainer} \times NUM_{Units}] \times PER_{Cost}$$

Parameter	Description
HOURS <sub>Non-Supervisory</sub>	Length of non-supervisory-level refresher training course (described in assumptions below)
HOURS <sub>Supervisory</sub>	Length of new refresher training course including behavioral observation (described in assumptions below)
NUM <sub>Employees</sub>	Annual number of employees per unit covered by FFD program (as described in Appendix 2, Exhibit A2-14)
NUM <sub>Units</sub>	Number of units per program (as described in Appendix 2, Exhibit A2-14)

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<sup>5</sup> Although many licensees may be conducting computer-based trainings, the analysis utilizes a class-based format, which may result in an overestimate of the cost of incremental training activities.

<b>Parameter</b>	<b>Description</b>
NUM <sub>Sessions</sub>	Annual number of refresher training sessions per unit (as described in assumptions below)
PER <sub>Cost</sub>	Percentage of cost applied to a given facility (as described in assumptions below)
PER <sub>Non-Supervisory</sub>	Percentage of employees trained at the non-supervisory level under the former rule (as described in assumptions below)
PER <sub>Refresher</sub>	Percentage of employees taking refresher training instead of the comprehensive “challenge” examination (described in assumptions below)
WAGE <sub>Trainer</sub>	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Worker</sub>	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Percentage of employees trained at the non-supervisory level under the former rule: 85%.
- Percentage of employees taking refresher instead of the comprehensive “challenge” examination: 20%.
- Length of new training course including behavioral observation: 4 hours.
- Length of non-supervisory-level training course per applicant: 2 hours.
- Annual number of supervisory-level refresher training sessions assumes 20 workers per session.
- Licensees have indicated that 75 percent of facilities already train all employees at this higher supervisory level and, therefore, would not incur any incremental cost under this requirement. Because the analysis cannot identify which facilities are already training at the higher level and which are not, the analysis assumes that each unit will incur the incremental cost of 25 percent of the activity.

**Paragraph 26.29(b)**

This final paragraph adds an explicit requirement to administer a comprehensive examination following FFD training. Although the former rule did not explicitly require comprehensive examinations, it did require licensees to ensure that training is achieving the desired results, and licensees normally accomplished this goal through examinations. Licensees have indicated that they already administer comprehensive examinations in order to ensure employee understanding. Thus, the clarified requirement to administer a comprehensive examination imposes no incremental cost and affords no saving. Note that even though there is no incremental cost to administer examinations, the content of the examination must now reflect new material, as discussed above in connection with paragraph 26.29(a). The cost of updating the training course itself also is addressed in connection with paragraph 26.29(a).

This final paragraph also requires that individuals who fail the comprehensive examination must take remedial training and retake the examination. The remedial training requires workers to review specific areas of the examination in which they performed poorly. Although licensees have indicated that they already retest non-supervisory individuals who fail the comprehensive examination, they may not be retraining them. Therefore, this analysis assumes that the new rule will result in incremental costs to retrain existing non-supervisory employees who fail the comprehensive examination following the updated training as well as those applicants for initial and update authorization who fail the examination after initial training.

Licensees will incur a *one-time cost* to require licensees to retrain individuals who fail the comprehensive examination after first taking the updated training addressing behavioral observation. The costs associated with the initial training update are calculated separately above. The *one-time cost per program* results from the following costs:

- One-time cost per program for employees to take remedial training after failing the initial comprehensive examination when updating their training is calculated as follows:

$$[NUM_{Employees} \times PER_{Non-Supervisory} \times PER_{Failing} \times HOURS_{Remedial} \times WAGE_{Worker}] \times NUM_{Units}$$

- One-time cost per program for trainers to administer remedial training on those employees who fail the initial comprehensive examination when updating training is calculated as follows:<sup>6</sup>

$$NUM_{Sessions} \times HOURS_{Remedial} \times WAGE_{Trainer} \times NUM_{Units}$$

Parameter	Description
HOURS <sub>Remedial</sub>	Length of remedial supervisory-level training (as described in assumptions below)
NUM <sub>Employees</sub>	Number of employees per unit (as described in Appendix 2, Exhibit A2-14)
NUM <sub>Units</sub>	Number of units per program (as described in Appendix 2, Exhibit A2-14)
NUM <sub>Sessions</sub>	Number of supervisory-level update training sessions per facility (as described in assumptions below)
PER <sub>Failing</sub>	Percentage of employees failing the comprehensive examination (as described in assumptions below)
PER <sub>Non-Supervisory</sub>	Percentage of employees trained at the non-supervisory level under the former rule (as described in assumptions below)
WAGE <sub>Trainer</sub>	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Worker</sub>	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

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<sup>6</sup> Although many licensees may be conducting computer-based trainings, the analysis utilizes a class-based format, which may result in an overestimate of the cost of incremental training activities.

- Length of remedial supervisory-level training: 0.75 hours.
- Percentage of employees trained at the non-supervisory level under the former rule: 85%.
- Percentage of employees failing comprehensive examination: 10%.
- Number of supervisory-level update retraining sessions per facility assumes 20 workers per session.

In addition to the one-time costs, licensees will incur an annual cost as a result of the new requirement to retrain all subsequent applicants who fail the comprehensive examination for initial and updated authorization. The *annual cost per program* results from the sum of the following costs:

- Annual cost per program for applicants to take remedial training after failing the initial comprehensive examination is calculated as follows:

$$NUM_{Applicants} \times PER_{Failing} \times HOURS_{Remedial} \times WAGE_{Worker} \times NUM_{Units}$$

- Annual cost per program for trainers to administer remedial training on applicants who fail the initial comprehensive examination is calculated as follows:<sup>7</sup>

$$NUM_{Sessions} \times HOURS_{Remedial} \times WAGE_{Trainer} \times NUM_{Units}$$

Parameter	Description
$HOURS_{Remedial}$	Length of remedial supervisory-level training (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants per unit who take the examination for initial and updated authorization (as described in Appendix 2, Exhibit A2-12)
$NUM_{Units}$	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$NUM_{Sessions}$	Annual number of supervisory-level training sessions per unit (as described in assumptions below)
$PER_{Failing}$	Percentage of applicants failing the comprehensive examination per year (as described in assumptions below)
$WAGE_{Trainer}$	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Length of remedial supervisory-level training: 0.75 hours.
- Percentage of applicants failing the comprehensive examination per year: 10%.

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<sup>7</sup> Although many licensees may be conducting computer-based trainings, the analysis utilizes a class-based format, which may result in an overestimate of the cost of incremental training activities.

- Number of supervisory-level training sessions per facility assumes 20 workers per session.

**Paragraph 26.29(c)**

***Subparagraph 26.29(c)(1)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely requires licensee employees to complete their training before being assigned activities under Part 26, as required under paragraph 26.21(b) of the former rule. Additionally, this final subparagraph eliminated a former provision to allow 3 months to upgrade training for newly assigned supervisors. The elimination of this provision will impose no additional cost because all employees will be required to train at the same supervisory level under paragraph 26.29(a).

***Subparagraph 26.29(c)(2)***

This subparagraph requires refresher training on a 12-month frequency, as required under paragraphs 26.21(b) and 26.22(c) of the former rule. Thus, no incremental cost or saving will result specifically from this requirement. However, the final subparagraph also adds a provision to allow workers to take a comprehensive annual examination in lieu of refresher training (i.e., a “challenge” exam). This provision represents potential incremental savings, as the examination requires less time to complete than the refresher training. The amount of the savings per employee depends on whether the employee who chooses to take the comprehensive examination is currently taking supervisory-level or non-supervisory-level refresher training. Although incremental savings are associated with workers taking less training, the savings will be partially offset because the cost of examination grading must be considered and subtracted. Licensees will also incur a one-time cost to develop procedures for administering the challenge examination, the cost of which is included in the calculations described in 26.29(a).

The *annual saving per program* results from the sum of the following savings:

- Annual saving per program for those employees choosing to take the shorter comprehensive examination in lieu of (the current non-supervisory-level) refresher training is calculated as follows:

$$\frac{NUM_{Employees} \times PER_{Non-Supervisory} \times PER_{Examination} \times (HOURS_{Non-Supervisory} - HOURS_{Exam}) \times WAGE_{Worker} \times NUM_{Units}}{}$$

- Annual saving per program for those employees choosing to take the shorter comprehensive examination in lieu of (the current supervisory-level) refresher training is calculated as follows.

$$\frac{NUM_{Employees} \times PER_{Supervisory} \times PER_{Examination} \times (HOURS_{Refresher} - HOURS_{Exam}) \times WAGE_{Worker} \times NUM_{Units}}{}$$

- Annual saving per program from reduced training costs due to employees choosing to take the shorter comprehensive examination in lieu of (the current non-supervisory-level) refresher training is calculated as follows:<sup>8</sup>

$$[NUM_{Sessions\ Non-Supervisory} \times (HOURS_{Non-Supervisory} + HOURS_{Preparation} - HOURS_{Exam} - HOURS_{Grading}) \times WAGE_{Trainer}] \times NUM_{Units}$$

- Annual saving per program from reduced training costs due to employees choosing to take the shorter comprehensive examination in lieu of (the current supervisory-level) refresher training is calculated as follows:

$$[NUM_{Sessions\ Supervisory} \times (HOURS_{Refresher} + HOURS_{Preparation} - HOURS_{Exam} - HOURS_{Grading}) \times WAGE_{Trainer}] \times NUM_{Units}$$

Parameter	Description
HOURS <sub>Exam</sub>	Length of comprehensive examination per exam (as described in assumptions below)
HOURS <sub>Grading</sub>	Hours of examination grading per session (as described in assumptions below)
HOURS <sub>Non-Supervisory</sub>	Length of non-supervisory-level refresher training course per session (as described in assumptions below)
HOURS <sub>Preparation</sub>	Hours of trainer time to prepare for training course per session (as described in assumptions below)
HOURS <sub>Refresher</sub>	Length of new refresher course per session (as described in assumptions below)
NUM <sub>Employees</sub>	Number of employees per unit (as described in Appendix 2, Exhibit A2-14)
NUM <sub>Units</sub>	Number of units per program (as described in Appendix 2, Exhibit A2-14)
NUM <sub>Sessions Supervisory</sub>	Annual number of comprehensive examination sessions per unit replacing supervisory-level refresher training (as described in assumptions below)
NUM <sub>Sessions Non-Supervisory</sub>	Annual number of comprehensive examination sessions per unit replacing non-supervisory-level refresher training (as described in Appendix 2, Exhibit A2-3)
PER <sub>Examination</sub>	Percentage of employees choosing to take comprehensive examination in lieu of refresher training (as described in assumptions below)
PER <sub>Non-Supervisory</sub>	Percentage of employees trained at the non-supervisory level under the former rule (as described in assumptions below)
PER <sub>Supervisory</sub>	Percentage of employees trained at the supervisory level under the former rule (as described in assumptions below)
WAGE <sub>Trainer</sub>	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Worker</sub>	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

<sup>8</sup> Although many licensees may be conducting computer-based trainings, the analysis utilizes a class-based format, which may result in an overestimate of the cost of incremental training activities.

*Assumptions:*

- Percentage of employees trained at the non-supervisory level under the former rule: 85%.
- Percentage of employees choosing to take the comprehensive examination in lieu of refresher training: 80%.
- Percentage of employees trained at the supervisory level under the former rule: 15%.
- Length of non-supervisory-level refresher training course per session: 2 hours.
- Length of comprehensive examination per exam: 0.5 hours.
- Length of new refresher course per session: 4 hours.
- Number of comprehensive examination sessions replacing refresher course assumes 20 workers per training session.
- Hours of trainer time to prepare for training course per session: 1 hour.
- Hours of examination grading per session: 0.5 hours.

***Subparagraph 26.29(c)(3)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because the added provision only authorizes licensees to conduct training via a variety of mediums. Alternative training mediums might allow licensees to take advantage of more effective and more efficient techniques. The final subparagraph clarifies the requirements in paragraph 26.21 of the former rule. Any savings that result from this provision are considered to be insignificant.

***Subparagraph 26.29(d)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely allows licensees to forego training and testing of individuals who have taken Part 26 training within the prior 12 months. The NRC and licensees have indicated that this provision is already practiced under the former rule, in accordance with guidance in NUREG-1385.

**26.31 Drug and Alcohol Testing**

**Paragraph 26.31(a)**

This paragraph of the final rule imposes no incremental cost or saving because it merely retains the requirements in paragraph 26.24(a) of the former rule which related to the implementation of

drug and alcohol testing programs for persons who are subject to this Subpart of the final rule.

**Paragraph 26.31(b)**

***Subparagraph 26.31(b)(1)***

This subparagraph amends Appendix A, Section 2.3 of the former rule to include FFD program personnel in the drug and alcohol testing program requirements. Incremental costs associated with adding FFD program personnel to the testing program are calculated in the discussion of subparagraph 26.4(g).

***Subparagraph 26.31(b)(1)(i)***

This final subparagraph revises the requirements in Appendix A, Section 2.3(2), of the former rule. The final rule clarifies that the background investigations, credit and criminal history checks, and psychological evaluations that are required for persons who are granted unescorted access to protected areas in nuclear power plants and other affected facilities are acceptable means for meeting this requirement addressing the honesty and integrity of FFD program personnel. The analysis assumes that a criminal history and credit check are included in the background check already required in order to grant unescorted access authorization under a licensee's access authorization program and, therefore, assumes no incremental cost. The final rule also relaxes a former provision that required licensees to update the background investigation every three years, thereby realizing an incremental saving. Although licensees must continue to update the psychological assessment and criminal history and credit checks, the final rule reduces the frequency of such updates from every 3 years to every 5 years, resulting in additional incremental savings.

The *annual saving per program* results from the *sum* of the following factors:

- The *base annual saving per program* (i.e., regardless of whether the program uses onsite or offsite collection facilities and testing laboratories) from eliminating the requirement to update background checks every 3 years is estimated as follows:

$$NUM_{Personnel-Base} \times COST_{Background\ Investigation\ Update} \times PER_{Annualized-1} \times NUM_{Units}$$

- Additional savings per program from eliminating the requirement to update background checks every 3 years *per program with onsite testing* are estimated as follows:

$$NUM_{Personnel-Onsite\ Testing} \times COST_{Background\ Investigation\ Update} \times PER_{Annualized-1} \times NUM_{Facilities}$$

- Additional savings per program from eliminating the requirement to update background checks every 3 years *per program with onsite collection* are estimated as follows:

$$NUM_{\text{Personnel-Onsite Collection}} \times COST_{\text{Background Investigation Update}} \times NUM_{\text{Facilities}} \times PER_{\text{Collection}} \times PER_{\text{Annualized-1}}$$

- *Base annual saving per program* (i.e., regardless of whether the program uses onsite or offsite collection and testing facilities) from reducing the frequency with which licensees must update the psychological evaluations and the criminal history and credit checks is estimated as follows:

$$NUM_{\text{Personnel-Base}} \times [COST_{\text{Criminal/Credit Update}} + COST_{\text{Psychological Evaluation Update}}] \times NUM_{\text{Units}} \times PER_{\text{Annualized-2}}$$

- Additional saving per program from reducing the frequency with which licensees must update the psychological evaluations and the criminal history and credit check *per program with onsite testing laboratories* is estimated as follows:

$$NUM_{\text{Personnel-Onsite-Testing}} \times [COST_{\text{Criminal/Credit Update}} + COST_{\text{Psychological Evaluation Update}}] \times PER_{\text{Annualized-2}} \times NUM_{\text{Facilities}}$$

- Additional saving per program from reducing the frequency with which licensees must update psychological evaluations and the criminal history and credit check update *per program with onsite collection facilities* is estimated as follows:

$$NUM_{\text{Personnel-Onsite-Collection}} \times [COST_{\text{Criminal/Credit Update}} + COST_{\text{Psychological Evaluations}}] \times PER_{\text{Collection}} \times PER_{\text{Annualized-2}} \times NUM_{\text{Facilities}}$$

Parameter	Description
$COST_{\text{Background Investigation Update}}$	Cost of updating an individual’s background investigations, excluding the credit check and criminal history check (as described in assumptions below)
$COST_{\text{Criminal/Credit Update}}$	Cost of updating an individual’s criminal and credit history (as described in assumptions below)
$COST_{\text{Psychological Evaluation Update}}$	Cost of updating an individual’s psychological evaluation (as described in assumptions below)
$NUM_{\text{Facilities}}$	Number of facilities per program (as described in Appendix 2, Exhibit A2-14)
$NUM_{\text{Personnel-Base}}$	Base number of FFD program personnel per unit for each program (as described in the assumptions below)
$NUM_{\text{Personnel-Onsite-Testing}}$	Additional number of FFD program personnel per facility for programs with onsite testing laboratories (as described in assumptions below)
$NUM_{\text{Personnel-Onsite-Collection}}$	Additional number of FFD program personnel per facility for programs with onsite collection facilities (described in assumption below)
$NUM_{\text{Units}}$	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{\text{Annualized-1}}$	Factor to adjust the periodic savings (every 3 years) to an annual savings (as described in assumptions below)

<b>Parameter</b>	<b>Description</b>
PER <sub>Annualized-2</sub>	Factor to adjust to the periodic savings (two updates eliminated every 15 years) to an annual savings (as described in assumptions below)
PER <sub>Collection</sub>	Percentage of facilities with onsite collection per program (as described in Appendix 2, Exhibit A2-1)

*Assumptions:*

- Base number of FFD program personnel (i.e., regardless of whether the program uses onsite or offsite collection facilities or testing laboratories) per unit: 1.5.
- Additional number of FFD program personnel per facility with onsite testing laboratories: 1.
- Additional number of FFD program personnel per facility for programs with onsite collection facilities: 0.5.
- Each facility in a program with onsite testing will have a separate testing laboratory with its own testing staff.
- Each facility in a program with onsite collection will have a separate collection site with its own collection staff.
- Cost of updating an individual’s background investigations (excluding the credit and criminal history check): \$150.
- Cost of updating an individual’s psychological evaluation: \$300.
- Cost of updating an individual’s criminal and credit history: \$50.
- Factor to annualize the 3-year periodic saving equals 1/3, or 33.3 percent (i.e., the final rule eliminates one background check update and one psychological evaluation, the savings of which are spread over 3 years).
- Factor to annualize the periodic saving from reducing a 3-year review frequency to a 5-year review frequency equals 2/15, or 13.3 percent (i.e., the final rule eliminates two criminal and credit history updates are eliminated, the savings of which are spread over 15 years).

*Subparagraph 26.31(b)(1)(ii)– (iv)*

These subparagraphs of the final rule impose no incremental cost and afford no saving because they merely amend the requirements in Appendix A, Section 2.3(1) of the former rule to prohibit assessment or evaluation by a person having a personal relationship with the donor or by an FFD

program supervisor or co-workers within the same work group of the individual being tested. The final subparagraphs add a requirement prohibiting determinations of fitness (discussed with respect to § 26.189) by FFD program personnel if the FFD program staff member has a personal relationship with the individual being tested. Specimen collection that does not require direct observation can be conducted by an individual who has a personal relationship with the donor so long as the collection process is monitored by a second individual who is trained to monitor specimen collections and the preparation of specimens for transfer or shipping and who does not have a personal relationship with the donor. When directly observed specimen collection is required, however, the collector may have no personal relationship with the donor.

***Subparagraph 26.31(b)(1)(v)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely restates the requirements in Appendix A, Section 2.3(3) of the former rule, which require licensees to subject all persons “responsible for administering the testing program” (including the MRO when on site) to a behavioral observation program.

***Subparagraph 26.31(b)(2)***

This subparagraph relaxes former requirements by authorizing FFD program personnel who are undergoing drug and alcohol testing to use collection services at a local hospital or other organization, provided that the facility conforms to DOT drug and alcohol testing requirements. This provision results in incremental cost and saving by allowing offsite FFD personnel (i.e., MROs) to utilize local collection services rather than traveling to the licensee’s facility. Specifically, licensees may incur higher testing costs at local collection facilities, as opposed to licensee testing facilities. This analysis assumes that the costs associated with periodic collections at non-licensee collection facilities will be greater than the collection cost at licensee facilities. Offsetting some of these costs, MROs and other offsite contracted personnel will experience reduced travel, waiting, and specimen collection time, on average.

The *annual cost per program* from allowing MROs and other offsite contracted personnel to utilize other facilities conforming to DOT requirements is calculated as follows:

$$[(NUM_{MROs} \times PER_{Random} \times PER_{Distance} \times (COST_{Local\ facility} - COST_{Licensee\ facility})] \times NUM_{Facilities}$$

<b>Parameter</b>	<b>Description</b>
$COST_{Local\ facility}$	Cost to conduct specimen collection at a local DOT-approved facility (as described in Appendix 2, Exhibit A2-13)
$COST_{Licensee\ facility}$	Cost to conduct specimen collection at the licensee facility (as described in Appendix 2, Exhibit A2-13)
$NUM_{Facilities}$	Number of facilities per program (as described in Appendix 2, Exhibit A2-14)
$NUM_{MROs}$	Number of offsite contracted MROs per facility (as described in assumptions below)

Parameter	Description
PER <sub>Distance</sub>	Percentage of contracted FFD personnel who live closer to a DOT-approved collection facility than to a licensee's standard collection facility (as described in assumptions below)
PER <sub>Random</sub>	Percentage tested by a random drug and alcohol testing program per year (as described in assumptions below)

*Assumptions:*

- Number of offsite contracted MROs per facility: 2.
- Percentage tested by a random drug and alcohol testing program per year: 50%.
- Percentage of contracted FFD personnel who live closer to a DOT-approved collection facility than to a licensee's standard collection facility: 33.3%.

The *annual saving per program* from allowing MROs and other offsite contracted personnel to utilize other facilities conforming to DOT requirements is calculated as follows:

$$[(NUM_{MROs} \times PER_{Random} \times PER_{Distance} \times (HOURS_{Travel} \times WAGE_{MRO}))] \times NUM_{Facilities}$$

Parameter	Description
HOURS <sub>Travel</sub>	Hours of travel, waiting, and specimen collection time (on average) saved by utilizing DOT-approved facility (as described in assumptions below)
NUM <sub>Facilities</sub>	Number of facilities per program (as described in Appendix 2, Exhibit A2-14)
NUM <sub>MROs</sub>	Number of offsite contracted MROs per facility (as described in assumptions below)
PER <sub>Distance</sub>	Percentage of contracted FFD personnel who live closer to a DOT-approved collection facility than to a licensee's standard collection facility (as described in assumptions below)
PER <sub>Random</sub>	Percentage tested by a random drug and alcohol testing program per year (as described in assumptions below)
WAGE <sub>MRO</sub>	MRO wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Number of offsite contracted MROs per facility: 2.
- Percentage tested by a random drug and alcohol testing program per year: 50%.
- Percentage of contracted FFD personnel who live closer to a DOT-approved collection facility than to a licensee's standard collection facility: 33.3%.

- Hours of MRO travel time saved by utilizing DOT-approved facility in lieu of the licensee’s collection site: 2 hours.

### **Paragraph 26.31(c)**

#### ***Subparagraph 26.31(c)(1)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies that licensees and other entities with licensee-approved FFD programs must administer pre-access drug and alcohol testing in order to grant initial, updated, and reinstated authorization as specified in § 26.65. Although pre-access testing is already required under 26.24(a)(1) of the former rule, the final rule adopts provisions from the AAO that create different requirements for individuals with different lengths of interruptions between periods of authorization. As a result, this subparagraph of the final rule imposes no incremental costs and affords no savings because it is based on non-safeguards information requirements imposed by the NRC’s AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

#### *Sensitivity Analysis-Pre-Order Baseline*

Relative to the regulations that were in effect before the NRC issued the AAO, the final subparagraph does not directly result in incremental costs or savings. The specific pre-access drug and alcohol testing requirements for the three authorization types are contained in § 26.65, and the incremental costs and savings of these requirements are calculated there.

#### ***Subparagraph 26.31(c)(2)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely describes the situations that warrant for-cause drug and alcohol testing, retaining provisions that are already included in subparagraph 26.24(a)(3) of the former rule.

#### ***Subparagraph 26.31(c)(3)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely describes situations that warrant post-event drug and alcohol testing, renumbering and clarifying provisions that are already included in subparagraph 26.24(a)(3) of the former rule. The final subparagraph does provide a new requirement establishing a threshold for the types of workplace personal injuries and illnesses for which post-event testing is required. Further, the final subparagraph changes a former requirement such that post-event testing is required regardless of whether there was “reasonable suspicion” that the individual was abusing drugs or alcohol for the consequences listed in the final paragraph.

#### ***Subparagraph 26.31(c)(4)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely prescribes that licensees must conduct followup drug and alcohol testing on individuals who have violated FFD policy in the past to ensure continued abstinence, as required under subparagraph 26.24(a)(4) of the former rule.

***Subparagraph 26.31(c)(5)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely rephrases requirements in subparagraph 26.24(a)(2) of the former rule and requires licensees to conduct random drug and alcohol testing on a statistically random and unannounced basis.

**Paragraph 26.31(d)**

***Subparagraph 26.31(d)(1)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely reorganizes paragraph 26.24(c) and Appendix A, Section 2.1(a)–(c), of the former rule. This revised subparagraph clarifies the six types of drugs for which each urine specimen must be analyzed and permits licensees and other entities to conduct testing for drugs or other substances that are not explicitly specified by the rule. The final subparagraph adds a requirement such that licensees and other entities must test for adulterants when conducting drug and alcohol testing.

***Subparagraph 26.31(d)(1)(i)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely retains the permission provided in paragraph 26.24(c) of the former rule for licensees to consult with local law enforcement or other sources to identify additional drugs that are likely to be used in the particular geographic locale of the FFD program. This final subparagraph also extends this permission to other entities with licensee-approved FFD programs and provides procedures for testing additional substances that are identified. The final subparagraph adds requirements that an independent and qualified forensic toxicologist must certify that testing results for other substances not explicitly identified by subparagraph 26.31(d)(1) are scientifically sound and legally defensible. The qualifications of the forensic toxicologist are also defined in this final paragraph. Although these additional testing requirements may result in additional costs, the identification of additional substances to test for is rare and the costs are, therefore, assumed to be negligible.

***Subparagraph 26.31(d)(1)(ii)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies that licensees and other entities are allowed to test for any suspected drugs, drug metabolites, or any other substances and adulterants that the licensee or other entity suspects that an individual may have abused when conducting post-event, followup, and for-cause testing. These requirements are already contained in Appendix A, Sections 2.1(b) and (e) of the former

rule. The new provision, however, adds a requirement that testing at the confirmatory assay’s LOD may only be performed if the initial test result suggests the presence of a drug or metabolite within 35% of the established cutoff concentration for drugs that the licensee or other entity suspects an individual may have abused. In addition, the final subparagraph specifies that test results that fall below the established cutoff levels may not be considered when determining appropriate management actions and sanctions (per Subpart D), except if the specimen is dilute and the licensee or other entity has requested the HHS-certified laboratory to evaluate the specimen under final §§ 26.163(a)(2) or 26.185(g)(3).

This limitation has been added to assure the privacy rights of individuals whose urine specimens may be tested under this provision. As licensees and other entities are already abiding by these protections, no incremental cost is anticipated.

*Subparagraph 26.31(d)(1)(iii)*

This subparagraph of the final rule requires licensee and other entities to document the additional drug(s) for which testing will be performed in written policies and procedures in which the substances for which testing will be performed are described. The incremental cost associated with this requirement is calculated within paragraph 26.27(a) of the final rule.

**Subparagraph 26.31(d)(2)**

This paragraph revises subparagraph 26.24(a)(2) of the former rule to clarify that licensees are required to ensure that all persons in the population subject to testing have an equal probability of being randomly selected and tested. Under the final subparagraph, in the event that a selected individual cannot be tested immediately, (i.e., on leave, out sick, etc.), the licensee must make reasonable efforts to test the individual at the earliest reasonable and practical opportunity when both the donor and collectors are available. Thus, licensees will incur an incremental cost to satisfy the “reasonable effort” requirement by tracking the randomly selected individuals who are unavailable during the selected testing date and testing them at the next (earliest) reasonable and practical opportunity. This final subparagraph also further clarifies that licensees must conduct testing on an unpredictable schedule, including weekends, backshifts, and holidays.” This provision imposes no additional costs because former subparagraph 26.24(a)(2) included these time periods, as described in Section 4.6 of NUREG-1385.

The *annual cost per program* from requiring greater effort to track individuals selected for random drug and alcohol testing results from the following:<sup>9</sup>

$$NUM_{Employees} \times PER_{Random} \times PER_{Unavailable} \times HOURS_{Manager} \times WAGE_{Manager} \times NUM_{Units}$$

Parameter	Description
HOURS <sub>Manager</sub>	Hours of FFD manager tracking time per randomly selected employee

<sup>9</sup> This analysis assumes that all licensees will be affected by the added provision. However, because some licensees may already be tracking and testing individuals unavailable at the time of random selection, the results may overestimate the true incremental cost.

<b>Parameter</b>	<b>Description</b>
	who is unavailable for the scheduled test (as described in assumptions below)
NUM <sub>Employees</sub>	Number of employees per unit (as described in Appendix 2, Exhibit A2-14)
NUM <sub>Units</sub>	Number of units per program (as described in Appendix 2, Exhibit A2-14)
PER <sub>Random</sub>	Percentage of employees per year who are randomly selected for drug and alcohol testing (as described in assumptions below)
PER <sub>Unavailable</sub>	Percentage of randomly selected employees per year who are unavailable for the scheduled test (as described in assumptions below)
WAGE <sub>Manager</sub>	FFD manager wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Percentage of employees per year who are randomly selected for drug and alcohol testing: 50%.
- Percentage of randomly selected employees per year who are unavailable for the scheduled test: 25%.
- Hours of FFD manager tracking time per randomly selected employee who is unavailable for the scheduled test: 0.25 hours.

***Subparagraph 26.31(d)(3)***

This subparagraph specifies general requirements for drug testing and combines paragraph 26.24(f) and Appendix A Sections 1.1(3), 2.8(e)(1), 4.1(a) and (b) of the former rule. An amendment adds validity testing, the costs of which are described under § 26.131 in Subpart F and subparagraph 26.161(b)(1) in Subpart G. This final subparagraph also establishes requirements for FFD programs that use more stringent cutoff levels for initial drug testing. (Each licensee and other entity must apply consistent cutoffs to all tests performed.) This final paragraph also requires documentation of the more stringent cutoff levels in the FFD program policy and procedures. The final subparagraph adds a new requirement such that, before implementing the more stringent cutoffs, an independent forensic toxicologist must evaluate and certify them as technically sound and legally defensible, with two exceptions. An evaluation by an independent forensic toxicologist is not required if the U.S. Department of Health and Human Services revises the cutoff levels in the HHS Guidelines and the FFD program adopts the lower HHS cutoffs. Certification by a forensic toxicologist also is not required if the licensee received written approval from NRC to test for lower cutoff levels before the implementation date of the final rule, in accordance with Appendix A, Section 1.1(2) of the former rule.

*The one-time cost per FFD program to employ more stringent cutoff level(s) for drugs results from the following:*

$$[(HOURS_{tox.review} + HOURS_{tox.report}) \times WAGE_{toxicologist}] \times PER_{more\ stringent\ cutoffs} \times PER_{non-report} + (HOURS_{Manager} \times WAGE_{Manager} \times PER_{more\ stringent\ cutoffs} \times PER_{non-report})$$

Parameter	Description
HOURS <sub>Manager</sub>	Hours of FFD program manager labor to review the results of the forensic toxicologist's evaluation of the FFD program's more stringent cutoff levels per program (as described in assumptions below)
HOURS <sub>tox.report</sub>	Hours of time spent by a forensic toxicologist to write an evaluation of the cutoff levels per FFD program (as described in assumptions below)
HOURS <sub>tox.review</sub>	Hours of review by a forensic toxicologist per FFD program using more stringent cutoff level(s) for drug testing (as described in assumptions below)
PER <sub>more stringent</sub>	Percentage likelihood that the FFD program uses more stringent cutoff levels for drug testing (as described in assumptions below)
PER <sub>non-report</sub>	Percentage likelihood that the FFD program, if it uses more stringent cutoff levels for drug testing, has not received NRC written approval (as described in assumptions below)
WAGE <sub>Manager</sub>	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>toxicologist</sub>	Toxicologist wage rate (as described in Appendix 2, Exhibit A2-11)

**Assumptions:**

- Hours of review by a forensic toxicologist per FFD program using more stringent cutoff level(s) for drug testing: 3.5 hours.
- Hours of time spent by a forensic toxicologist to write an evaluation of the cutoff levels per FFD program: 0.5 hours.
- Hours of time spent by FFD program manager to review the results of the forensic toxicologist's evaluation per FFD program: 0.5 hours.
- Percentage likelihood that the FFD program will use more stringent cutoff levels for drug testing after the final rule is enacted: 10 percent.
- Percentage likelihood that the FFD program, if it will use more stringent cutoff levels for drug testing after the final rule is enacted, did not previously use these more stringent cutoff levels (and, therefore, has not received Commission approval): 25 percent.

**Subparagraph 26.31(d)(4)**

This subparagraph revises requirements in 26.24(g) of the former rule, which pertained to alcohol testing. Specifically, this revised subparagraph modifies the applicable threshold requirement by reducing the threshold level of breath alcohol concentration from 0.04 to 0.02 for an initial breath test requiring confirmatory testing. Incremental costs associated with this

revision are calculated and discussed in connection with § 26.97. Another revision permits the use of oral fluids for initial breath testing and is discussed in § 26.95 of this analysis.

***Subparagraph 26.31(d)(5)***

This subparagraph permits the MRO to authorize alternative specimen collection and evaluation procedures in instances in which an individual has a medical condition that makes it difficult or hazardous to collect breath, oral fluids, or urine specimens. Although this clarification offers licensees more flexibility in collecting specimens, the analysis assumes that these situations are extremely rare, making any potential savings speculative and negligible.

***Subparagraph 26.31(d)(6)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it restates that specimens collected can only be used for Part 26 testing, and clarifies that specimens may only be collected and tested within a licensee or licensee-approved other entity FFD program that meets the requirements of this part, as required by Section 2.1(d) of Appendix A of the former rule.

**26.33 Behavioral Observation**

This section of the final rule represents a new requirement, which requires that individuals with authorization (i.e., other than supervisors, managers, and escorts as required under subparagraph 26.27(b)(10)) are required to report fitness concerns to persons designated by the licensee. Costs associated with behavioral observation training are calculated in connection with § 26.29. In addition, the new behavioral observation requirements and the additional requirement for individuals with authorization to report FFD concerns about other individuals who are present at the licensee’s or other entity’s site or facility may result in additional for-cause referrals. As a result, there will be an increase in both the number of drug and alcohol tests performed, and the number of positive test results that must undergo confirmatory testing. The analysis calculates the cost of these activities below. The observation and reporting provisions of this final paragraph impose no incremental cost and afford no saving.

The *annual cost per program* results from the sum of the following costs:

- Annual cost per program to review additional for-cause referrals is calculated as follows:

$$NUM_{For-Cause} \times PERI_{For-Cause} \times [(HOURS_{Worker} \times WAGE_{Worker}) + (HOURS_{Manager} \times WAGE_{Manager})] \times NUM_{Units}$$

- Annual cost per program to conduct additional drug and alcohol tests due to increased for-cause referrals is calculated as follows:<sup>10</sup>

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<sup>10</sup> The increased costs will vary for programs depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

- Annual cost per program to conduct additional drug and alcohol tests due to increased for-cause referrals at programs with onsite testing laboratories (yielding negative results) results from the following:

$$NUM_{For-Cause} \times PERI_{For-Cause} \times PER_{Negative} \times COST_{Onsite-Negative} \times NUM_{Units}$$

- Annual cost per program to conduct additional drug and alcohol tests due to increased for-cause referrals at programs with offsite testing laboratories (yielding negative results) results from the following:

$$NUM_{For-Cause} \times PERI_{For-Cause} \times PER_{Negative} \times COST_{Offsite-Negative} \times NUM_{Units}$$

- Annual cost per program to conduct additional drug and alcohol tests due to increased for-cause referrals at programs with onsite testing laboratories (yielding non-negative results) results from the following:

$$NUM_{For-Cause} \times PERI_{For-Cause} \times (1 - PER_{Negative}) \times COST_{Onsite-Non-Negative} \times NUM_{Units}$$

- Annual cost per program to conduct additional drug and alcohol tests due to increased for-cause referrals at programs with offsite testing laboratories (yielding negative results) results from the following:

$$NUM_{For-Cause} \times PERI_{For-Cause} \times (1 - PER_{Negative}) \times COST_{Offsite-Non-Negative} \times NUM_{Units}$$

- Annual cost per program to retest confirmed positive drug test results at a second HHS-certified laboratory at the request of the donor is calculated as follows:

$$NUM_{For-Cause} \times PERI_{For-Cause} \times (1 - PER_{Negatives}) \times PER_{Retest} \times COST_{Retest} \times NUM_{Units}$$

- Annual cost per program for the percentage of workers with confirmed positive test results who initiate an appeals process is calculated as follows:

$$NUM_{For-Cause} \times PERI_{For-Cause} \times (1 - PER_{Negatives}) \times PER_{Appeals} \times COST_{Appeals} \times NUM_{Units}$$

<b>Parameter</b>	<b>Description</b>
$COST_{Appeals}$	Cost of appeals process per appeal (as described in Appendix 2, Exhibit A2-11, Exhibit A2-13)
$COST_{Offsite-Negative}$	For-cause testing cost for a negative result per test at programs with offsite testing laboratories (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{Offsite-Non-Negative}$	For-cause testing cost for a non-negative result per test at programs with offsite testing laboratories (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{Onsite-Negative}$	For-cause testing cost for a negative result per test at programs with onsite testing laboratories (as described in assumptions below and in Appendix 2, Exhibit A2-13)

<b>Parameter</b>	<b>Description</b>
	laboratories (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{\text{Onsite-Non-Negative}}$	For-cause testing cost for a non-negative result per test at programs with onsite testing laboratories (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{\text{Retest}}$	Cost of drug retest per test (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$HOURS_{\text{Manager}}$	Hours of FFD program manager review per for-cause referral (as described in assumptions below)
$HOURS_{\text{Worker}}$	Hours of facility worker hours under review per for-cause referral (as described in assumptions below)
$NUM_{\text{For-Cause}}$	Pre-rule annual number of for-cause tests/referrals per unit (as described in Appendix 2, Exhibit A2-12)
$NUM_{\text{Units}}$	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{\text{Appeals}}$	Percentage of workers who have positive test results and initiate an appeals process (as described in assumptions below and in Appendix 2, Exhibit A2-6)
$PERI_{\text{For-Cause}}$	Percentage increase in for-cause tests/referrals as a result of the final rule (as described in assumptions below)
$PER_{\text{Negative}}$	Percentage of for-cause tests that yield negative test results (as described in Appendix 2, Exhibit A2-12)
$PER_{\text{Retest}}$	Percentage of workers who have positive test results and request retesting (as described in assumptions below)
$WAGE_{\text{Manager}}$	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{\text{Worker}}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Percentage increase in for-cause tests/referrals beginning with new rule: 10%.
- Hours of facility worker hours under review per for-cause referral: 4 hours per review.
- Hours of FFD program manager review per for-cause referral: 4 hours per review.
- Percentage of workers who have positive test results and request retesting: 5%.
- Percentage of workers who have positive test results and initiate an appeals process: 1%.
- The per-unit cost of an *onsite for-cause drug and alcohol test yielding negative results* includes the following factors:
  - (1) travel time of the worker

- (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  - (3) onsite licensee testing costs per urine specimen for drugs and validity
  - (4) labor of FFD manager to process paperwork for negative test results.
- The per-unit cost of an *offsite for-cause drug and alcohol test yielding negative results* includes including the following factors:
  - (1) travel time of the worker
  - (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  - (3) HHS-certified laboratory costs per urine specimen for drugs and validity;
  - (4) labor of FFD manager to process paperwork for negative test results
- The per-unit cost of an *onsite for-cause drug and alcohol test yielding positive results* includes the following factors:
  - (1) travel time of the worker
  - (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  - (3) onsite licensee testing costs per urine specimen for drugs
  - (4) HHS-certified laboratory cost per specimen for drugs and validity
  - (5) cost of subsequent actions resulting from a confirmatory positive drug/validity test result
- The per-unit cost of an *offsite for-cause drug and alcohol test yielding positive results* includes the following factors:
  - (1) travel time of the worker
  - (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  - (3) HHS-certified laboratory costs per urine specimen for drugs and validity
  - (4) cost of subsequent actions resulting from a confirmatory positive drug/validity test result

## **26.35 Employee Assistance Programs**

### **Paragraph 26.35(a)**

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely restates and clarifies the language in § 26.25 of the former rule, which requires licensees and other entities to have employee assistance programs (EAPs).

### **Paragraph 26.35(b)**

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies language in § 26.25 of the former rule, which requires that licensees and other entities are not required to provide EAP services to C/V employees nor to individuals who have

applied for, but have not yet been granted, authorization.

### **Paragraph 26.35(c)**

This paragraph of the final rule [including subparagraphs 26.35(c)(1)–(3)] imposes no incremental cost and affords no saving because it merely restates and clarifies the language in § 26.25 of the former rule regarding the role of EAP staff in protecting the identity and privacy of any individual’s seeking assistance. The new paragraph does allow the EAP to bypass the privacy requirement in the event that the individual waives the right to privacy in writing or if a determination of fitness deems an individual’s condition or actions pose or have posed an immediate hazard to himself or herself or others. In such cases, EAP personnel shall inform FFD management. The final paragraph also adds specificity to the former rule, providing examples of individual conditions or actions that require EAP personnel to report the individual to management. This final paragraph parallels elements covered in § 26.25 of the former rule.

## **26.37 Protection of Information**

### **Paragraph 26.37(a)**

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely combines and clarifies wording from paragraph 26.29(a) and Appendix A, Section 3.1, of the former rule.

### **Paragraph 26.37(b)**

This paragraph of the final rule [including subparagraphs 26.37(b)(1)–(8)] imposes no incremental cost and affords no saving because it restates and separates elements of paragraph 26.29(b) of the former rule.

### **Paragraph 26.37(c)**

This paragraph of the final rule requires licensees and other entities to disclose personal information collected under this part to other licensees or other entities, including C/Vs, legitimately seeking the information for authorization decisions. As indicated by NRC guidance in NUREG-1600, “Revision to the NRC Enforcement Policy” (per 67 FR 66311, October 31, 2002) licensees are already sharing this information. The analysis also assumes that C/Vs are already sharing such information with other C/Vs. Whether licensees are sharing information with C/Vs is unknown, but such instances are assumed to be rare. Therefore, the final paragraph imposes no incremental cost and affords no saving.

### **Paragraph 26.37(d)**

This paragraph combines elements of paragraph 26.29(b) of the former rule to clarify information disclosure requirements for individuals. Although the former rule required similar disclosure processes, some licensees interpreted the former provisions in a manner that

complicates the process through which employees can have access to their records. In an effort to clarify the NRC’s original intent, the revised paragraph requires the FFD program (including, but not limited to, the collection site, HHS-certified laboratory, substance abuse expert, or MRO) to give requesting individuals copies of all of their own FFD records, including but not limited to records pertaining to a violation of FFD policy. The copying, packaging, and shipping of these records will result in an incremental cost to licensees.

The *annual cost per program* to provide individuals with easier access to personal documents results from the following:<sup>11</sup>

$$NUM_{Positives} \times PER_{Requesting} \times [(HOURS_{Clerical} \times WAGE_{Clerical}) + COST_{Mailing}] \times NUM_{Units}$$

Parameter	Description
COST <sub>Mailing</sub>	Cost of mailing (express mail) per information disclosure request (as described in Appendix 2, Exhibit A2-6)
HOURS <sub>Clerical</sub>	Additional clerical personnel hours to copy, package, and ship records per disclosure request (as described in assumptions below)
NUM <sub>Positives</sub>	Annual number of drug tests yielding positive results per unit (as described in Appendix 2, Exhibit A2-12)
NUM <sub>Unit</sub>	Number of units per program (as described in Appendix 2, Exhibit A2-14)
PER <sub>Requesting</sub>	Percentage of employees who have positive test results and request records (as described in assumptions below)
WAGE <sub>Clerical</sub>	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- For the purposes of this analysis, it is assumed that individuals request their own FFD records only when they are found in violation of FFD policy.
- Percentage of employees who have positive test results and request records: 50%.
- Additional clerical personnel hours to copy, package, and mail records per disclosure request: 1 hour.

**Paragraph 26.37(e)**

This paragraph of the final rule imposes no incremental cost and affords no saving because it retains a portion of Section 3.1 of Appendix A to the former rule.

**Paragraph 26.37(f)**

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<sup>11</sup> The analysis assumes that all licensees will incur costs as a result of this provision. However, because some licensees may already be providing adequate access to records, the results may overestimate the true incremental cost.

This paragraph of the final rule imposes no incremental cost and affords no saving because it retains a portion of paragraph 26.29(b) of the former rule.

### **26.39 Review Process for Fitness-for-Duty Policy Violations**

#### **Paragraph 26.39(a)**

This paragraph of the final rule, which states that an objective and impartial review process for FFD policy violations must be established, imposes no incremental cost and affords no saving because any incremental costs associated with revising or rewriting procedures are calculated in connection with § 26.27. The final paragraph, however, adds requirements to the language in paragraph 26.28 of the former rule by requiring an objective and impartial review of the facts.

#### **Paragraph 26.39(b)**

This paragraph of the final rule imposes no incremental cost and affords no saving because it requires that an individual under review must be allowed to offer additional relevant information, as provided under § 26.28 of the former rule.

#### **Paragraph 26.39(c)**

This paragraph requires that a review of potential FFD policy violations be conducted by an individual who is not associated with FFD program administration. Under the subparagraph 26.27(b)(3) of the former rule, licensees were required to establish satisfactory management and medical assurance of an individual's fitness for duty before granting unescorted access following a previous violation of policy. According to NRC guidance contained in NUREG-1385, "Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions," licensees were free to interpret how best to meet the "satisfactory assurance" requirement, which at a minimum involves a review by a single individual. This paragraph of the final rule imposes no incremental cost and affords no saving because it retains the intent of subparagraph 26.27(b)(3) of the former rule.

#### **Paragraph 26.39(d)**

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely requires licensees to update their records in the event that review finds in favor of the individual. Further, the final paragraph clarifies paragraph 26.28 of the former rule, which implicitly required corrections of records after a successful appeal.

#### **Paragraph 26.39(e)**

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies provisions in paragraph 26.28 of the former rule. Specifically, this final paragraph states that when a C/V is administering an FFD program on which licensees and other entities rely, and the C/V determines that its employee, subcontractor, or applicant has violated

its FFD policy, the C/V must ensure that the review procedure required in this section is provided to the individual. In addition, this final paragraph states that licensees who rely on a C/Vs FFD program are *not* required to give C/V employees a review procedure for violations identified through a C/V’s drug and alcohol testing program.

**26.41 Audits and Corrective Action**

**Paragraph 26.41(a)**

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies the licensee’s responsibility for ensuring the continued effectiveness of all elements of the FFD program, including programs and program elements implemented by C/Vs, as well as programs implemented by HHS-certified laboratories. These requirements are addressed in connection with paragraph 26.80 of the former rule.

**Paragraph 26.41(b)**

This paragraph reduces the audit frequency for licensees and other entities (with onsite collection services) from every 12 months under paragraph 26.80(a) of the former rule to “as needed, but no less frequently than every 24 months,” resulting in a potential incremental savings. Total annual savings will depend on whether a given licensee has onsite or offsite collection and testing facilities (i.e., because the final rule [in paragraph 26.41(c)(1)] does not reduce the frequency of licensee audits of HHS-certified laboratories or offsite collection facilities that do not maintain their own FFD program). The reduced audit frequency will also yield savings from reduced auditor travel costs, which are calculated separately below.

The *annual saving per program*, excluding travel savings (which are calculated separately later in the discussion), is calculated as the *sum* of the following factors:

- The *annual base saving per program* (regardless of whether the program uses onsite or offsite testing and collection facilities) from the reduced audit frequency is estimated as follows:

$$[(HOURS_{Auditor-Base} \times WAGE_{Auditor}) + (HOURS_{Manager-Base} \times WAGE_{Manager}) + (HOURS_{Clerical-Base} \times WAGE_{Clerical})] \times PER_{Annualized} \times NUM_{Facilities}$$

- The additional *annual saving per program* from the audit frequency reduction that accrue to programs with *onsite testing* is estimated as follows:

$$[(HOURS_{Auditor-Onsite\ Testing} \times WAGE_{Auditor}) + (HOURS_{Manager-Onsite\ Testing} \times WAGE_{Manager}) + (HOURS_{Clerical-Onsite\ Testing} \times WAGE_{Clerical}) + (HOURS_{Lab\ Manager} \times WAGE_{Lab\ Manager}) + (HOURS_{Lab\ Staff} \times WAGE_{Lab\ Staff})] \times PER_{Annualized} \times NUM_{Facilities}$$

- The additional *annual saving per program* from the audit frequency reduction that accrue *to programs with onsite collection* is estimated as follows:

$$\begin{aligned}
 & [(HOURS_{Auditor-Onsite\ Collection} \times WAGE_{Auditor}) + (HOURS_{Manager-Onsite\ Collection} \times \\
 & WAGE_{Manager}) + (HOURS_{Clerical-Onsite\ Collection} \times WAGE_{Clerical}) + [NUM_{Facilities} \times \\
 & ((HOURS_{Collection\ Manager} \times WAGE_{Collection\ Manager}) + (HOURS_{Collection\ Staff} \times WAGE_{Collection \\
 & Staff ))]] \times PER_{Collection} \times PER_{Annualized} \times NUM_{Facilities}
 \end{aligned}$$

Parameter	Description
HOURS <sub>Auditor-Base</sub>	Base hours of contracted auditor time that each facility saves per full program audit (as described in assumptions below)
HOURS <sub>Auditor-Onsite Collection</sub>	Additional hours (i.e., above the base described previously) of contracted auditor time saved per full program audit of a facility with onsite collection facilities (as described in assumptions below)
HOURS <sub>Auditor-Onsite Testing</sub>	Additional hours (i.e., above the base described previously) of contracted auditor time saved per full program audit of a facility with onsite testing laboratories (as described in assumptions below)
HOURS <sub>Clerical-Base</sub>	Base hours of clerical personnel time that each facility saves per full program audit (as described in assumptions below)
HOURS <sub>Clerical-Onsite Collection</sub>	Additional hours (i.e., above the base described previously) of clerical personnel time saved per full program audit of a facility with onsite collection facilities (as described in assumptions below)
HOURS <sub>Clerical-Onsite Testing</sub>	Additional hours (i.e., above the base described previously) of clerical personnel time saved per full program audit of a facility with onsite testing laboratories (as described in assumptions below)
HOURS <sub>Collection Staff</sub>	Hours of collection site staff time saved per full program audit of a facility with onsite collection facilities (as described in assumptions below)
HOURS <sub>Collection Manager</sub>	Hours of collection site manager time saved per year per facility with onsite collection facilities (as described in assumptions below)
HOURS <sub>Lab Manager</sub>	Hours of testing laboratory manager time saved per full program audit of a facility with onsite testing laboratories (as described in assumptions below)
HOURS <sub>Lab Staff</sub>	Hours of testing laboratory staff time saved per full program audit of a facility with onsite testing laboratories (as described in assumptions below)
HOURS <sub>Manager-Base</sub>	Base hours of FFD program manager time that each facility saves per full program audit (as described in assumptions below)
HOURS <sub>Manager-Onsite Testing</sub>	Additional hours (i.e., above the base described previously) of FFD program manager time saved per full program audit of a facility with onsite testing laboratories (as described in assumptions below)
HOURS <sub>Manager-Onsite Collection</sub>	Additional hours (i.e., above the base described previously) of FFD program manager time saved per full program audit of a facility with onsite collection facilities (as described in assumptions below)
NUM <sub>Facilities</sub>	Number of facilities per program (as described in Appendix 2, Exhibit A2-14)
PER <sub>Annualized</sub>	Percentage multiplier to yield annualized savings

<b>Parameter</b>	<b>Description</b>
	(as described in assumptions below)
$PER_{Collection}$	Percentage of facilities with onsite collection per program (as described in Appendix 2, Exhibit A2-4)
$WAGE_{Auditor}$	Contract auditor wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Collection\ Manager}$	Collection site manager wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Collection\ Staff}$	Collection site staff wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Lab\ Staff}$	Laboratory staff wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Lab\ Manager}$	Laboratory manager wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Manager}$	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Percentage multiplier to yield annualized savings is 50% because the frequency reduction allows facilities to eliminate 1 audit over a 2-year period.
- Base hours of contracted auditor time that each facility saves per full program audit: 25 hours.
- Base hours of FFD program manager time that each facility saves per full program audit: 13 hours.
- Base hours of clerical personnel time that each facility saves per full program audit: 5 hours.
- Additional hours (i.e., above the base described above) of contracted auditor time saved per full program audit of a facility with onsite testing laboratories: 12 hours.
- Additional hours (i.e., above the base described above) of FFD program manager time saved per full program audit of a facility with onsite testing laboratories: 7 hours.
- Additional hours (i.e., above the base described above) of clerical personnel time saved per full program audit of a facility with onsite testing laboratories: 0 hours.
- Each program with onsite testing maintains a separate onsite testing laboratory.

- Additional hours (i.e., above the base described above) of contracted auditor time saved per full program audit of a facility with onsite collection facilities: 5 hours.
- Additional hours (i.e., above the base described above) of FFD program manager time saved per full program audit of a facility with onsite collection facilities: 0 hours.
- Additional hours (i.e., above the base described above) of clerical personnel time saved per full program audit of a facility with onsite collection facilities: 0 hours.
- Hours of testing laboratory manager time saved per full program audit of a facility with onsite testing laboratories: 2 hours.
- Hours of testing laboratory staff time saved per full program audit of a facility with onsite testing laboratories: 1 hours.
- Hours of collection site manager time saved per full program audit of a facility with onsite collection facilities: 2 hours.
- Hours of collection site staff time saved per full program audit of a facility with onsite collection facilities: 1 hour.
- Each facility in a program with onsite collection maintains a separate onsite collection site.

The audit frequency reduction will also result in reduced travel costs. The *annual saving per program* results from the sum of the following savings:

- The reduced audit frequency will result in reduced travel costs for auditors. The associated *annual base savings per program* from the reduced travel at each facility (i.e., regardless of whether a program uses onsite or offsite collection facilities and testing laboratories) are calculated as follows:

$$[NUM_{Auditors-Base} \times (COST_{Travel} + (COST_{Lodging} \times NUM_{Nights-Base}) + (HOURS_{Travel} \times WAGE_{Auditor}))] \times PER_{Annualized}$$

- Additional annual saving per program that accrue due to reduced auditor travel to facilities with *onsite testing laboratories* is estimated as follows:

$$NUM_{Auditors-Onsite\ Testing} \times COST_{Lodging} \times NUM_{Nights-Onsite\ Testing} \times PER_{Annualized}$$

- Additional annual saving per program that accrue due to reduced auditor travel to facilities with *onsite collection facilities* is estimated as follows:

$$NUM_{Auditors-Onsite\ Collection} \times COST_{Lodging} \times NUM_{Nights-Onsite\ Collection} \times PER_{Collection} \times$$

*PER*<sub>Annualized</sub>

<b>Parameter</b>	<b>Description</b>
$COST_{Lodging}$	Cost of lodging and per diem per night (as described in assumptions below)
$COST_{Travel}$	Cost of round trip travel per auditor per audit (as described in assumptions below)
$HOURS_{Travel}$	Hours of round trip travel auditor per audit (as described in assumptions below)
$NUM_{Auditors-Base}$	Base number of auditors per program audit (as described in assumptions below)
$NUM_{Auditors-Onsite\ Testing}$	Additional number of auditors per program with onsite testing laboratories (as described in assumptions below)
$NUM_{Auditors-Onsite\ Collection}$	Additional number of auditors per program with onsite collection facilities (as described in assumptions below)
$NUM_{Nights-Base}$	Base number of nights of lodging that each program saves per full program audit (as described in assumptions below)
$NUM_{Nights-Onsite\ Testing}$	Additional number of nights of lodging each program saves per full program audit of a program with onsite collection and offsite testing (as described in assumptions below)
$NUM_{Nights-Onsite\ Collection}$	Additional number of nights of lodging each program saves per full program audit of a program with offsite collection and offsite testing (as described in assumptions below)
$PER_{Annualized}$	Percentage multiplier to yield annual savings (as described in assumptions below)
$PER_{Collection}$	Percentage of facilities with onsite collection per program (as described in Appendix 2, Exhibit A2-4)
$WAGE_{Auditor}$	Auditor wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Base number of auditors per program audit (regardless of whether the program uses onsite or offsite collection sites and testing laboratories): 1.
- Additional number of auditors per program with onsite testing laboratories: 1.
- Additional number of auditors per program with onsite collection facilities: 0.<sup>12</sup>
- Cost of round trip travel per auditor per audit: \$300.
- Cost of lodging and per diem per night: \$150.

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<sup>12</sup> Programs with onsite testing laboratories are also believed to operate onsite collection facilities. In this case, the additional auditor calculated for the onsite collection facility is also assumed to audit the onsite testing facility.

- Hours of round trip travel per auditor per audit: 4 hours.
- Base number of nights of lodging each program saves per full program audit: 3 nights.
- Additional number of nights of lodging each program saves per full program audit of a program with onsite testing laboratories: 1 night.
- Additional number of nights of lodging each program saves per full program audit of a program with onsite collection facilities: 0 nights.
- Percentage multiplier to yield annualized savings is 50% because the frequency reduction allows facilities to eliminate 1 audit over a 2-year period.
- Each facility in a program with onsite collection maintains a separate onsite collection site.

Although licensees and other entities with approved FFD programs are allowed to audit less frequently, they are expected to conduct additional auditing activities when performance indicators suggest a potential area of weakness in the FFD program. The cost of these additional, focused audits, which targets specific FFD program activities and requires a shorter amount of time to complete than a full program audit, partially offsets the savings resulting from the reduced frequency of full program audits. The *annual cost per program* to conduct focused audits addressing problem areas of the FFD program results from the following:

$$[(HOURS_{Focused\ Auditor} \times WAGE_{Auditor}) + (HOURS_{Focused\ Manager} \times WAGE_{Manager}) + (HOURS_{Focused\ Clerical} \times WAGE_{Clerical})] \times NUM_{Facilities} + [NUM_{Auditors} \times (COST_{Travel} + (COST_{Lodging} \times NUM_{Nights-Focused}) + (HOURS_{Travel} \times WAGE_{Auditor}))]$$

Parameter	Description
$COST_{Lodging}$	Cost of lodging and per diem per night (as described in assumptions below)
$COST_{Travel}$	Cost of round trip travel per focused audit (as described in assumptions below)
$HOURS_{Focused\ Clerical}$	Hours of clerical personnel time per focused audit per facility (as described in assumptions below)
$HOURS_{Focused\ Manager}$	Hours of FFD program manager time per focused audit per facility (as described in assumptions below)
$HOURS_{Focused\ Auditor}$	Hours of contracted auditor time per focused audit per facility (as described in assumptions below)
$HOURS_{Travel}$	Hours of round trip auditor travel per focused audit (as described in assumptions below)
$NUM_{Auditors}$	Number of auditors per focused audit

<b>Parameter</b>	<b>Description</b>
	(as described in assumptions below)
NUM <sub>Facilities</sub>	Number of Facilities per program (as described in Appendix 2, Exhibit A2-14)
NUM <sub>Nights-Focused</sub>	Number of nights of lodging required by the auditor to complete a focused audit (as described in assumptions below)
WAGE <sub>Auditor</sub>	Contract auditor wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Clerical</sub>	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Manager</sub>	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Hours of contracted auditor time conducting a focused audit per facility: 4 hours.
- Hours of FFD program manager time per a focused audit per facility: 3 hours.
- Hours of clerical personnel time conducting a focused audit per facility: 1 hours.
- Number of auditors per focused audit: 2.
- Cost of round trip travel per focused audit: \$300.
- Cost of lodging and per diem per night: \$150.
- Hours of round trip auditor travel per focused audit: 4 hours.
- Number of nights of lodging required by the auditor to complete a focused audit: 1 night.

**Paragraph 26.41(c)**

***Subparagraph 26.41(c)(1)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies that C/Vs located offsite or not under the direct supervision or observation of licensee personnel must be audited at a 12-month frequency, as specified in paragraph 26.80(a) of the former rule. The C/V services subject to this requirement include contracted MRO services, EAP or specimen collection services, and the services provided by HHS-certified laboratories. As described and calculated in 26.41(b), those C/V services that are provided onsite under the direct daily supervision of licensee personnel will be audited at a frequency of at least once every 24 months.

**Subparagraph 26.41(c)(2)**

This subparagraph adds a provision that allows licensees and other entities to rely upon the HHS certification reports and audits of HHS-certified laboratories, thereby eliminating audit duplication. Services provided to the licensee or other entity not addressed in the certification review must continue to be audited. Further duplication is eliminated by exempting organizations that do not routinely provide FFD services to a licensee or other entity, such as local hospitals or substance abuse treatment facilities. The elimination of audit duplication under this final subparagraph will result in incremental savings.

The *annual saving per program* from eliminating audit duplication results from the following:

$$(HOURS_{Auditor} \times WAGE_{Auditor}) + (HOURS_{Manager} \times WAGE_{Manager}) + (HOURS_{Clerical} \times WAGE_{Clerical})$$

Parameter	Description
HOURS <sub>Auditor</sub>	Hours of contracted auditor time saved annually per program in elimination of audit duplication (as described in assumptions below)
HOURS <sub>Clerical</sub>	Hours of clerical personnel time saved annually per program in elimination of audit duplication (as described in assumptions below)
HOURS <sub>Manager</sub>	Hours of FFD program manager time saved annually per program in elimination of audit duplication (as described in assumptions below)
WAGE <sub>Auditor</sub>	Contracted auditor wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Clerical</sub>	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE <sub>Manager</sub>	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)

*Assumptions:*

- Hours of contracted auditor time saved annually per program in elimination of audit duplication: 7 hours.
- Hours of FFD program manager time saved annually per program in elimination of audit duplication: 4 hours.
- Hours of clerical personnel time saved annually per program in elimination of audit duplication: 1 hour.

**Paragraph 26.41(d)**

**Subparagraph 26.41(d)(1)**

This subparagraph of the final rule imposes no incremental cost and affords no saving because it

merely restates the provision in Appendix A, Section 2.7(m) of the former rule regarding the reservation of the right to audit C/Vs, the C/V's subcontractors providing FFD services, and the HHS-certified laboratories at any time.

***Subparagraph 26.41(d)(2)***

This subparagraph of the final rule adds a new requirement stating that licensees' and other entities' contracts with C/Vs or HHS-certified laboratories must permit the licensee or other entity to obtain copies of any documents to assure that the C/V or the laboratory are performing their functions properly and that staff and procedures meet applicable requirements. The C/V or HHS-certified laboratory, however, does have the ability to reasonably limit the use and dissemination of any documents to ensure the protection of proprietary information and donors' privacy. Although not explicitly required in the former rule, the analysis assumes that current industry practices provide for the sharing of such information. As a result, no incremental costs or savings result from this final subparagraph.

***Subparagraph 26.41(d)(3)***

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely restates requirements in Appendix A, Section 2.7(m) of the former rule. The final subparagraph requires licensees to conduct pre-award inspections and audits of the procedural aspects of HHS laboratory operations, except as provided in 26.41(g)(5), discussed below.

**Paragraph 26.41(e)**

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely states that audits must focus on the effectiveness of FFD programs and auditors must remain independent of FFD program management and other personnel responsible for implementing the FFD program, as required by paragraph 26.80(b) of the former rule.

**Paragraph 26.41(f)**

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely states licensees must document audit results and report them to senior corporate and site management, who must take and document appropriate corrective actions, including possible re-auditing of deficient areas (as discussed in paragraph 26.41(b)). These provisions are contained in paragraph 26.80(c) of the former rule.

**Paragraph 26.41(g)**

This paragraph of the final rule [including subparagraphs 26.41(g)(1)–(5)] imposes no incremental cost and affords no saving because it clarifies and/or explicitly sets forth implementation requirements under paragraph 26.80(a) of the former rule, and permitted practices regarding the sharing of audits. Subparagraph 26.41(g)(5) allows licensees and other entities to immediately use another HHS-certified laboratory in the event that their contracted

HHS-laboratory loses its certification (the effect of which is discussed in paragraph 26.153(e) of this analysis).