

Subpart N: Recordkeeping and Reporting Requirements

26.709 Applicability

This section of the final rule imposes no incremental cost and affords no saving because it merely states that the requirements of Subpart N apply to the FFD programs of licensees and other entities specified in final § 26.3, except for FFD programs that are implemented under Subpart K.

26.711 General Provisions

Paragraph 26.711(a)

This paragraph of the final rule restates former requirements, presented in §§ 26.71 and 26.73 of the former rule, which stated that licensees and other entities that have approved FFD programs must maintain records and submit reports to the NRC. The final paragraph adds a provision specifying that required records must be retained until license termination if the rule does not specify another retention period. Although this may extend the period of retention of certain records (depending on current licensee practices), the most substantial costs associated with retaining the records (filing, removal, etc.) do not change as a result of this final paragraph. The incremental burden of maintaining the necessary storage space for those particular records until the time of license termination is insignificant to this analysis.

Paragraph 26.711(b)

This paragraph of the final rule adds provisions to allow licensees to use electronic recordkeeping. Although this provision may result in savings for some licensees, such savings are likely to be small and are not calculated for purposes of this analysis.

Paragraph 26.711(c)

This paragraph of the final rule requires licensees and other entities to inform individuals of the right to review and correct the records maintained about the individual under this part and imposes a requirement on licensees and other entities to ensure that the information they maintain and share with other licensees and entities is correct and complete. This paragraph of the final rule is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order (AAO) dated January 7, 2003, and published in the Federal Register on January 13, 2003. As a result, the final paragraph imposes no incremental costs and affords no savings.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph does not result in any incremental costs. Although the final paragraph adopts provisions from the AAO that require licensees and other entities to inform individuals of their right to review FFD information about the individual, this analysis assumes that this is a standard business practice

for licensees and other entities. Therefore, the analysis anticipates that this new requirement will not result in any additional costs.

Paragraph 26.711(d)

This paragraph of the final rule requires licensees and other entities to ensure that only correct and complete information about individuals is retained and shared with other licensees and other entities. In addition, this paragraph requires that licensees and other entities must correct or augment the shared information used to determine an individual's eligibility for authorization if the information changes or new information is developed. This paragraph of the final rule is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order (AAO) dated January 7, 2003, and published in the Federal Register on January 13, 2003. As a result, the final paragraph imposes no incremental costs and affords no savings.

Sensitivity Analysis - Pre-Order Baseline

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26.713 Recordkeeping Requirements for Licensees and Other Entities

Paragraphs 26.713(a)

This paragraph of the final rule [including subparagraphs (1)–(4)] requires that records of self-disclosures, employment histories, and suitable inquiries that are required under §§ 26.55, 26.57, 26.59, and 26.69 as well as those pertaining to denials and granting of authorization, be retained for a period of at least 5 years or until completion of any related legal proceeding, whichever is later. Although extending the period of retention beyond 5 years represents a new requirement, the most substantial costs associated with retaining the records (filing, removal, etc.) do not change as a result of this final paragraph. The incremental burden of maintaining the necessary storage space for those particular records for which legal proceedings continue beyond the 5 year period is insignificant to this analysis. In addition, the ability to store these records electronically under subparagraph 26.711(b) will likely reduce or offset the potential costs associated with the longer retention period.

Paragraphs 26.713(b)

This paragraph of the final rule [including subparagraphs (1) and (2)] requires that records of trainings conducted under § 26.29 as well as audits, audit findings, and corrective actions taken under § 26.41, be retained for a period of at least 3 years or until completion of any related legal

proceeding, whichever is later. Although extending the period of retention beyond 3 years in the case of legal proceedings represents a new requirement, the most substantial costs associated with retaining the records (filing, removal, etc.) do not change as a result of this final paragraph. The additional burden of maintaining the necessary storage space for those particular records beyond the 3 year period is insignificant to this analysis. In addition, the ability to store these records electronically under subparagraph 26.711(b) will likely reduce or offset the potential costs associated with the longer retention period.

Paragraphs 26.713(c)

This paragraph of the final rule extends to 40 years (or until the NRC deems adequate) the period for which licensees must retain records pertaining to any 5-year denial of authorization under paragraph 26.75(c), (d), or (e)(2) and any a permanent denial of authorization under paragraphs 26.75(b) and 26.75(g). Paragraph 26.71(c) of the former rule imposed similar requirements, but specified a minimum 3-year period for retaining records. Despite this difference, however, removal of records still requires a management determination that the records are no longer needed. The most substantial costs associated with retaining the records (filing, removing, etc.) do not change as a result of the final rule. Although licensees will incur some additional burden to maintain the necessary storage space for 40 years instead of 3 years, these costs are insignificant to this analysis. In addition, the ability to store these records electronically under subparagraph 26.711(b) will likely reduce or offset the potential costs associated with the longer retention period.

Paragraphs 26.713(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely revises requirements in § 26.20 of the former rule, which pertained to retaining for at least three years records of written, superceded FFD policies and procedures. By contrast, the final rule extends the retention period to 5 years or until completion of all legal proceedings related to the FFD policy violation. The most substantial cost associated with retaining the records (filing, removing, etc.) do not change as a result of the new rule. Although licensees will incur some additional burden to maintain the necessary storage space for 5 years instead of 3 years, these costs are insignificant to this analysis. In addition, the ability to store these records electronically under subparagraph 26.711(b) will likely reduce or offset the potential costs associated with the longer retention period.

Paragraphs 26.713(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely retains the requirement that written agreements between licensees and other entities must be stored for the life of the agreement. The final paragraph also adds that licensees must retain such agreements until the completion of all legal proceedings related to FFD violations that involve those services, if that is later than the life of the agreement. This revision is consistent with long-term licensee practices relating to documents governing FFD-related contracts. Consequently, no incremental cost or saving results.

Paragraphs 26.713(f)

This paragraph of the final rule requires that records of background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel, conducted under § 26.31(b)(1)(i) be retained for the length of the individual’s employment by or contractual relationship with the licensee or other entity, or until the completion of all related legal proceedings, whichever is later. Although this represents a new requirement, the incremental burden associated with retaining the necessary records is insignificant to this analysis. In addition, the ability to store these records electronically under subparagraph 26.711(b) will likely reduce or offset the potential costs associated with the paragraph.

Paragraphs 26.713(g)

This paragraph of the final rule requires that licensees or other entities whose FFD program includes tests for drugs in addition to those specified in the final rule, or uses more stringent cutoff levels than those specified in the final rule, retain documentation certifying the scientific and technical suitability of the assays and cutoff levels used, as required under §§ 26.31(d)(1)(i) and 26.31(d)(3)(iii)(C). This paragraph of the final rule represents a new requirement, and imposes incremental costs associated with filing and retaining the specified documentation for the length of time the FFD program follows these practices or until the completion of all related legal proceedings, whichever is later. The cost of retaining documentation of these procedures, once filed, is negligible.

The *one-time cost per program* results from clerical support to file and store the forensic toxicologist’s evaluation of the FFD program’s more stringent cutoff levels.

$$HOURS_{Clerical} \times WAGE_{Clerical} \times PER_{more\ stringent\ cutoffs} \times PER_{non-report}$$

Parameter	Description
HOURS _{Clerical}	Hours of clerical personnel to file and store the forensic toxicologist’s evaluation of the FFD program’s more stringent cutoff levels per program (as described in assumptions below)
PER _{more stringent cutoffs}	Percentage likelihood that the FFD program uses more stringent cutoff levels for drug testing (as described in assumptions below)
PER _{non-report}	Percentage likelihood that the FFD program, if it uses more stringent cutoff levels for drug testing, has not reported to the Commission (as described in assumptions below)
WAGE _{Clerical}	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of clerical personnel to file and store the forensic toxicologist’s evaluation per program: 15 minutes.

- 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 reported to the Commission): 25 percent.

26.715 Recordkeeping Requirements for Collection Sites, Licensee Testing Facilities, and Laboratories Certified by the Department of Health and Human Services

Paragraphs 26.715(a) and 26.715(b)

These paragraphs of the final rule impose no incremental cost and afford no saving because they merely restate requirements in § 26.71 and Appendix A Sections 2.5(f), 2.6(c), and 2.7(n) of the former rule. Specifically, these paragraphs of the former rule required collection sites, licensee testing facilities, and HHS-certified laboratories to maintain documentation concerning all aspects of the testing process (including personnel files for individuals who have been authorized to have access to specimens but are no longer under contract to or employed by the entity) for at least 2 years. The final paragraph adds that collection sites, licensee testing facilities, and HHS-certified laboratories must also retain such records until the completion of any legal proceedings related to an FFD violation, if that is later than the 2-year period. Nonetheless, the most substantial costs associated with retaining the records (filing, removing, etc.) do not change as a result of the new rule. Although licensees will incur some additional burden to store these records for a longer period in certain instances, these costs are insignificant to this analysis.

26.717 Fitness-for-Duty Program Performance Data

Paragraph 26.717(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely restates requirements in paragraph 26.71(d) of the former rule, which pertained to the collection and compilation of FFD program performance data.

Paragraph 26.717(b)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely renumbers requirements in paragraph 26.71(d) of the former rule, which specified the performance data that licensees and C/Vs must compile and collect under paragraph 26.717(a). Although this revised paragraph does add a provision requiring FFD programs to report the number of subversion attempts by type, the rarity of such events makes the incremental cost insignificant.

Paragraph 26.717(c)

This paragraph of the final rule requires licensees and other entities to analyze performance data annually. Incremental costs and savings attributable to this provision are analyzed under related paragraphs 26.717(e) and (f). Licensees and other entities also must retain records of the data, analyses, and corrective actions taken for at least 3 years or until the completion of any related legal proceedings, whichever is later. Although the provision to record corrective actions taken is not contained in the former rule, no incremental costs are expected to result because the burden of recording such events is incidental to that of the corrective actions themselves.

Paragraph 26.717(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely restates requirements in paragraph 26.71(d) of the former rule, which addressed how licensees must report information on terminations of authorization or other administrative actions resulting from positive drug tests to the NRC.

Paragraph 26.717(e) and 26.717(f)

These paragraphs of the final rule require FFD programs to report performance data to the NRC every 12 months, rather than every 6 months as specified under the former regulation. The new requirement represents an incremental savings in that it requires licensees to prepare and submit to the NRC only one performance data report (instead of two) each year. Paragraph 26.717(f) allows licensees to submit the FFD program performance data as a consolidated report, provided that the data are reported separately for each facility. There is no incremental cost or saving associated with this latter report consolidation provision.¹

The *annual saving per program* associated with eliminating one performance data report per year is calculated as follows:

$$HOURS_{Manager} \times WAGE_{Manager} \times NUM_{Facilities}$$

Parameter	Description
HOURS _{Manager}	FFD program manager hours saved in reducing the reporting frequency per facility (as described in assumptions below)
NUM _{Facilities}	Number of units at the given facility (as described in Appendix 2, Exhibit A2-14)
WAGE _{Manager}	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)

Assumption:

¹ The analysis assumes that licensees will not opt to change their reporting practices if doing so increases costs. Savings are assumed not to accrue given that licensees must still report data separately for each facility addressed in the consolidated report.

- FFD program manager hours saved in reducing the reporting frequency per facility: 20 hours.

The NRC also will experience savings under this final paragraph. Under the former rule, performance reports were submitted twice each year. As the NRC received the performance reports, clerical personnel process and file them in a manner that facilitates annual review by an NRC manager. On an annual basis, the NRC manager reads, reviews, and summarizes the performance reports in an annual industry report. The reduction in the frequency of performance reports will result in savings for the NRC. The *annual saving to the NRC* from processing fewer licensee reports is calculated as follows:

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

Parameter	Description
HOURS _{Clerical}	NRC clerical hours saved in reducing the reporting frequency per year (as described in assumptions below)
HOURS _{Manager}	NRC manager hours saved in reducing the reporting frequency per year (as described in assumptions below)
WAGE _{Clerical}	NRC clerical wage rate (as described in Appendix 2, Exhibit A2-11)
WAGE _{Manager}	NRC manager wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- NRC manager hours saved in reducing the reporting frequency per year: 20 hours.
- NRC clerical hours saved in reducing the reporting frequency per year: 24 hours.

Paragraph 26.717(g)

This paragraph of the final rule adds a requirement that includes C/Vs in the reporting of performance data, but precludes duplicate information from being submitted to the NRC. Currently, C/Vs who maintain their own FFD programs are reporting performance data to multiple licensees for whom they work. Incremental savings will result from the paragraph because it will reduce the number of report summaries that C/Vs must distribute each year.

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

- The final paragraph will reduce the C/V manager labor burden because managers will be able to submit to the NRC a single report that consolidates all performance data that the C/V previously prepared for each licensee. The associated costs are estimated as follows:

$$HOURS_{Manager} \times WAGE_{Manager} \times PER_{Consolidation}$$

- The final paragraph will reduce mailing costs because C/Vs will only need to submit a single performance data report to the NRC. The associated savings are estimated as follows:

$$(NUM_{Licensees} - 1) \times COST_{Mailing}$$

Parameter	Description
$COST_{Mailing}$	Cost of mailing (express mail) one performance data report to each licensee (as described in Appendix 2, Exhibit A2-10)
$HOURS_{Manager}$	Hours of C/V manager time to compile all licensee performance data reports (as described in assumptions below)
$NUM_{Licensees}$	Number of licensees to whom each C/V submits performance data under the former rule (as described in assumptions below)
$PER_{Consolidation}$	Percentage savings achieved by consolidating performance data into a single report submitted to the NRC (as described in assumptions below)
$WAGE_{Manager}$	C/V manager wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Number of licensees to whom each C/V submits performance data to under the former rule: 9.
- Hours of C/V manager time to compile all licensee performance data reports: 30 hours.
- Percentage savings achieved by consolidating performance data into a single report submitted to the NRC: 25%.
- Under the former rule, C/Vs submitted performance data reports to each licensee for whom they work, but not to the NRC. Under the final rule, C/Vs will opt to report only to the NRC.

26.719 Reporting Requirements

Paragraphs 26.719(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies that licensees must report to the NRC all significant violations of the FFD policy (as required in § 26.73 of the former rule), significant FFD program failures, and errors in drug and alcohol testing (as required in Appendix A, Sections 2.8(e)(4)–(6) of the former rule). The revised paragraph also clarifies that other entities (C/Vs) who have licensee-approved FFD programs must also report significant violations, failures, or errors to the NRC.

Paragraph 26.719(b)

This paragraph of the final rule [including subparagraphs (1)–(4)] lists the significant FFD policy violations and program failures that must be reported to the NRC Operations Center. Under the clarifications in § 26.719(b)(2)(ii), additional reportable FFD policy violations may result in incremental costs per FFD program because of:

- the reduction in the non-negative breath alcohol concentration (BAC) level for initial alcohol testing from 0.04 to 0.02 BAC as discussed in § 26.97(b),
- the reduction in the initial cutoff level for marijuana metabolites from 100 ng/mL to 50 ng/mL (somewhat offset by raising of the initial cutoff level for opiate metabolites from 300 ng/mL to 2,000 ng/mL) as discussed in §§ 26.133 and 26.163(a)(1), and
- the addition of validity testing on all urine specimens as discussed in §§ 26.131 and 26.161(b).

Incremental costs will result from the added time that the FFD program manager must spend to collect, analyze, and report information concerning the additional events.

The *annual cost per program* associated with the increase in reported FFD events is calculated as follows:

$$NUM_{Events} \times PER_{Staff} \times (HOURS_{Manager} \times WAGE_{Manager}) \times NUM_{Units}$$

Parameter	Description
HOURS _{Manager}	FFD program manager hours required to investigate, analyze, and report a FFD event (as described in assumptions below)
NUM _{Events}	Annual number of additional non-negative specimen test results for validity and drugs testing per unit under the final rule (as described in Appendix 2)
NUM _{Units}	Number of units at the given facility (described in Appendix 2)
PER _{Staff}	Percentage of tested staff subject to reporting provisions of § 26.719(b)(2) (as described in assumptions below)
WAGE _{Manager}	FFD program manager wage rate (described in Appendix 2)

Assumptions:

- Percentage of tested staff subject to reporting provisions of § 26.719(b)(2): 15%.
- FFD program manager hours required to investigate, analyze, and report an event: 4 hours.

The NRC also will incur incremental costs as a result of the additional reportable events. The increase in the number of reported FFD events will result in additional reports being sent to the NRC, as required by paragraph 26.719(a), thereby increasing the labor burden associated with

processing and reviewing the licensee reports. The NRC’s *annual cost* is calculated as follows:

- The NRC manager labor burden will increase as a result of the increased number of reported FFD events. The associated costs are estimated as follows:

$$NUM_{Events} \times PER_{Staff} \times (HOURS_{Manager} \times WAGE_{Manager}) \times NUM_{Units}$$

Parameter	Description
HOURS _{Manager}	NRC manager hours required to review a reported FFD event (as described in assumptions below)
NUM _{Events}	Annual number of additional non-negative specimen test results for validity and drugs testing per unit under the final rule (as described in Appendix 2)
NUM _{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
PER _{Staff}	Percentage of tested staff subject to reporting provisions of 26.719(b)(2) (as described in assumptions below)
WAGE _{Manager}	NRC program manager wage (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of tested staff subject to reporting provisions of § 26.719(b)(2): 15%.
- NRC manager hours required to review a reported FFD event: 3 hours.

Paragraph 26.719(c)

Subparagraph 26.719(c)(1)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely retains and renumbers requirements in Appendix A, Sections 2.8(e)(4)–2.8(e)(6) of the former rule, which stated that licensees must report to the NRC within 30 days of completing an investigation of testing errors or unsatisfactory performance in blind performance testing.

Subparagraph 26.719(c)(2)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies that the requirement in former paragraph 26.73(a) involving the reporting of significant FFD events includes reporting false positive errors on a blind performance test specimen submitted to an HHS-certified laboratory.

Subparagraph 26.719(c)(3)

This subparagraph of the final rule requires licensees to report to NRC within 24 hours in the event of a false negative during quality assurance checks of validity screening tests. Although

this represents a new requirement, it imposes no incremental cost and affords no saving for the foreseeable future because there currently are no approved validity screening devices that can be used by licensees (as discussed in more detail under § 26.131).

Paragraph 26.719(d)

This paragraph of the final rule requires licensees to document, trend, and correct other non-reportable FFD issues that identify programmatic weaknesses under the licensee's corrective action program in a manner that will not permit the identification of individuals. Although not explicitly required under the former rule, the analysis assumes that licensees and other entities are already tracking and trending FFD program weaknesses in their corrective action programs. As a result, the final paragraph imposes no incremental cost and affords no saving.