Regulatory Analysis for the Drug & Alcohol Testing Portions of the FFD Rule

Brian J. Richter
Reactor Policy & Rulemaking Program
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation
July 7, 2004

Changes in Assumptions for Regulatory Analysis (Drug and Alcohol)

Affected Section	Previous Assumption or Approach	New Assumption or Approach	Reason for Change
Global	41 FFD programs	36 FFD programs	Updated information available in NUREG-1350-Vol. 15, 2003
26.29(b)	Individuals who fail training exams will repeat the entire training and exam	Individuals who fail training exams will repeat only the portion(s) of the training and exam that correspond to the failed portions of the initial exam	Feedback from the previous stakeholder meeting
26.29(b)	Length of supervisory-level training: 3.67 hours Length of non-supervisory-level training: 2.25 hours Length of comprehensive examination: 0.4 hours Length of non-supervisory-level refresher training: 0.9 hours	Length of supervisory-level training: 4.0 hours Length of non-supervisory-level training: 2.0 hours Length of comprehensive examination: 0.5 hours Length of non-supervisory-level refresher training: 1.0 hours	Rounded the previous assumptions
26.87(b)	Half of all programs will incur a one-time cost of $50,000 each to implement visual privacy for breath alcohol collections	No calculable costs. Visual privacy applies only to the test results, so results can be shielded using readily available office supplies	Feedback from the previous stakeholder meeting

Changes in Assumptions for Regulatory Analysis
(Drug and Alcohol)
(cont.)

26.89(c)	(No equivalent provision)	No incremental cost for collectors to inform donors that non-cooperation will be considered as a refusal to test	Providing this instruction will take only take seconds per collection; non-cooperation will be rare due to the serious consequences
26.91(b)-(c)	Each site will purchase two evidential-grade breath alcohol analysis devices (EBTs)	Each site will purchase one EBT	Feedback from the previous stakeholder meeting
26.91(b)-(c)	Lower EBT equipment costs	Higher EBT equipment costs	Recent research
Various	Lower validity testing costs	Higher validity testing costs	Recent research based on feedback from the previous stakeholder meeting
26.187	Wage rate for substance abuse expert (SAE) is less than that for medical review officer (MRO)	Wage rate for the SAE is the same as that for MRO	Feedback from the previous stakeholder meeting

Review of OMB Clearance Assumptions

- OMB encourages an agency to obtain up to 9 separate estimates for the numbers in the Paperwork Reduction Act Clearance.

- Clearance tables for Part 26 (Alcohol and Drug Testing) estimating average burden have been prepared.
    - Reporting Requirements
    - Recordkeeping Requirements

- Estimates in Tables based on:
    - OMB Clearance for the current FFD rule, approved by OMB in 2001
    - Assumptions from the regulatory analysis for the proposed Part 26 revisions, and
    - Staff's best estimate

OMB Clearance Assumptions:
Part 26 Recordkeeping Requirements

(Estimates are per FFD Program per year unless otherwise noted)

26.27(b) Revise written FFD policy statement to reflect revised Part 26	One time; 80 hours
26.27(c) Revise written FFD procedures to reflect revised Part 26	One time; 520 hours
26.27(a) Maintain written FFD policy and procedures	Covered under 26.213(d)
26.29(a) Develop training materials addressing specified knowledge and abilities (KAs)	One time; 210 hours
26.29(b) Develop comprehensive examination	One time; 40 hours
26.29(c) Develop refresher training	One time; 80 hours
26.29(c) Maintain records of training	Covered under 26.213(b)
26.31(b)(1)(ii) Maintain records of background investigations, credit and criminal history checks, and psychological evaluations of FFD program personnel	2 hours
26.31(d)(1)(D), 26.31(d)(1)(D)(ii), (d)(3)(iii)(A), and (d)(3)(iii)(C) Maintain written certification by forensic toxicologist of assay and cutoff levels (new)	2 hours
26.31(d)(6) Maintain written permissions by donors for specimens collected under NRC regulations to be used to conduct analysis or testing not described in Part 26	1 hour

OMB CLEARANCE ASSUMPTIONS: PART 26 RECORDKEEPING REQUIREMENTS (continued)

(Estimates are per FFD Program per year unless otherwise noted)

26.35(c) Maintain written waivers by individuals seeking assistance from the EAP of right to privacy	1 hour
26.37(a) Development of procedures to protect personal information collected to comply with Part 26	One time/ Previously completed
26.37(b) Maintain signed consents authorizing the disclosure of personal information collected and maintained under Part 26	1 hour
26.37(b)(1) Maintain written designations by individuals of representatives for specified FFD matters	1 hour
26.39(a) Development of procedure for the review of a determination that an individual has violated a FFD policy	One time; 40 hours
26.41(f) Maintain documentation of the results of audits and recommendations	Covered under 26.213(b)(2)
26.41(f) and (g)(4) Maintenance of audit records	Covered under 26.213(b)(2)
26.61(a) Preparation and maintenance of written self-disclosures and employment histories from individuals applying for authorization	15 hours to prepare Maintenance of record covered under 26.213(a)(1)
26.61(a)(2) Preparation of written self-disclosure from individual applying for authorization whose last period of authorization was terminated with the previous 29 days	10 hours to prepare Maintenance of record covered under 26.213(a)(1)

OMB CLEARANCE ASSUMPTIONS: PART 26 RECORDKEEPING REQUIREMENTS (continued)

(Estimates are per FFD Program per year unless otherwise noted)

26.63(a) and (e) Prepare and maintain record of suitable inquiry	5 hours to prepare Maintenance of record covered under 26.213(a)(1)
26.63(c)(2) Maintain hand-carried copy of form DD 214 presented by individual to support suitable inquiry	1 hour
26.63(c)(3) Maintain documentation by licensee or other entity conducting suitable inquiry of refusal to provide information by company, previous employer, or educational institution	1 hour
26.65(g) and 26.75(h)(3) Elimination of any matter from an individual's personnel record and other records that could link an individual to a temporary administrative action that has been reversed	Covered under 26.213(a)(2) and 26.213(a)(4)
26.69 Obtaining self-disclosures, suitable inquiry, and other records necessary to either grant or maintain an individual's authorization when potentially disqualifying FFD information has been disclosed or discovered	15 hours to prepare Maintenance of record covered under 26.213(a)(1)
26.85(b) Development of training materials for alcohol collector qualification training	One time,16 hours
26.197(b)(1) Maintenance of procedures on process for addressing self-declarations of fatigue (new)	*Addressed in fatigue background paper*
26.197(b)(2) Maintenance of procedures for implementing work hour controls required under 26.199 (new)	*Addressed in fatigue background paper*

OMB CLEARANCE ASSUMPTIONS: PART 26 RECORDKEEPING REQUIREMENTS (continued)

(Estimates are per FFD Program per year unless otherwise noted)

26.197(d)(1) Records of work hours for individuals subject to work hour controls in 26.199 (new)	*Addressed in fatigue background paper*
26.197(d)(2) Records of waivers granted in accordance with 26.199(e)(3) (new)	*Addressed in fatigue background paper*
26.197(d)(3) Records of work hour reviews conducted in accordance with 26.199(g) (new)	*Addressed in fatigue background paper*
26.197(d)(4) Records of fatigue assessments conducted in accordance with 26.201(d) (new)	*Addressed in fatigue background paper*
26.213(a)(1) Records of self-disclosures and suitable inquiries under §§26.61, 26.63, and 26.69 that result in the granting of authorization (formerly 26.71(a) pertaining to records under former 26.27(a))	20 hours to prepare 1 hour to maintain
26.213(a)(2) Records pertaining to denials of authorization (formerly 26.71(c) pertaining to decisions under 26.27(b)(2), (3), (4), or 26.27(c)) 12 hours to prepare	1 hour to maintain
26.213(a)(3) Records pertaining to the determination of a violation of the FFD policy and related management actions (formerly 26.71(b))	4 hours
26.213(a)(4) Documentation of the granting of authorization (formerly not explicitly required)	8 hours
26.213(b) Records of FFD training and examinations under 26.29 (formerly 26.21c) and 26.22(c))	120 hours
26.213(b)(2) Records of audits, audit findings and corrective actions taken under 26.41 (formerly 26.80(c))	36 hours

OMB CLEARANCE ASSUMPTIONS: PART 26 RECORDKEEPING REQUIREMENTS (continued)

(Estimates are per FFD Program per year unless otherwise noted)

26.213(c) Records of permanent denials of authorization under 26.75(b) and 26.75(g) (formerly 26.71(c))	4 hours
26.213(d) Record of written FFD policy and procedures under 26.27(a) and (c) (formerly 26.20 initial unnumbered paragraph)	1 hour
26.213(d) Record of any superseded FFD policy or procedure (formerly 26.20 initial unnumbered paragraph)	0.5 hour
26.213(e) Record of written agreements [contracts] for the provision of services (formerly 26.23, 26.28, 26.70)	0.5 hour
26.215(a) Documentation of all aspects of the testing process at collection sites providing services to licensees and other entities and licensee testing facilities. Includes: Subpart E – Collecting Specimens for Testing	558 hours

OMB CLEARANCE ASSUMPTIONS: PART 26 RECORDKEEPING REQUIREMENTS (continued)

(Estimates are per FFD Program per year unless otherwise noted)

26.93 (Documentation that the instructions for alcohol testing were communicated to the individual) 26.95(b)(5) (Retention of record of result of alcohol test) 26.97(b) (Record of reason for new breath test if steps in 26.97(a) could not be completed successfully) 26.97(d) (Record of result of alcohol test and record that ASD was used) 26.99(b) (Record of time at which test result of 0.02 BAC or higher is known) 26.101 (b)(7) (Record of result of confirmatory test for alcohol) 26.107(b) (Document on custody-and-control form conduct indicating attempt to tamper with specimen) 26.111(c) (Note any unusual findings with respect to urine specimen on custody-and-control form) 26.115(d) (Complete new custody-and-control form for specimen obtained from direct observation, including reasons for the observed collection 26.117(c) (Prepare and apply identification label) 26.117(d) and (e) (Complete custody-and-control form)	

OMB CLEARANCE ASSUMPTIONS: PART 26 RECORDKEEPING REQUIREMENTS (continued)

(Estimates are per FFD Program per year unless otherwise noted)

Subpart F – Licensee Testing Facilities 26.125(b) and (c) (Document proficiency of technicians who perform urine specimen testing) 26.127(a) (Develop and maintain procedures for accession, receipt, shipment, and testing of urine specimens) 267.127(b) (Develop and maintain written chain-of- custody procedures) 26.127(c) (Develop and maintain standard operating procedures for each assay for drug and specimen validity testing) 26.127(d) (Develop and maintain written procedures for instrument and device setup and normal operation) 26.127(e) (Develop and maintain written procedures for remedial actions when systems or devices are out of acceptable limits or errors are detected, and document that these procedures are followed) 26.129(a) (Document authorization of individuals with authorized access to secured areas of licensee testing facility) 26.137(a) (Develop quality assurance program for licensee testing facility 26.137(b)(1)(ii) (Maintain documentation demonstrating that testing device meets performance testing requirements) 26.137(e)(8) (Document the implementation of procedures to ensure that carryover does not contaminate the testing of a donor's specimen) 26.137(f) (Prepare record of investigations and corrective actions taken of any testing errors or unsatisfactory performance of the testing process)	

OMB CLEARANCE ASSUMPTIONS: PART 26 RECORDKEEPING REQUIREMENTS (continued)

(Estimates are per FFD Program per year unless otherwise noted)

Does not include laboratories certified by HHS (Subpart G) because information collection requirements for quality assurance and quality control, security and chain of custody; documentation, performance testing, and inspections are covered by HHS submission to the Office of Management and Budget for Mandatory Guidelines for Federal Workplace Drug Testing Programs.	
26.217 Collection of performance data (formerly 26.71(d))	20 hours

OMB CLEARANCE ASSUMPTIONS: PART 26 REPORTING REQUIREMENTS

(* denotes estimate from 2001 OMB clearance; **+** denotes estimate derived from Regulatory Analysis for revised Part 26)

26.9 Exemption application (formerly 26.6)	16 hours per application* Total of 2 licensees request exemption each year*
26.35(c) Notice by EAP staff to licensee that employee's condition presents hazard (formerly 26.25)	0.5 hour per notice* Total of 18 such notices per year*
26.37(c) Disclosure of information collected under Part 26 to another licensee or other entity for authorization decisions (formerly 26.29(b)	0.1 hour per disclosure 475 applicants for updated or reinstated authorization per program per year+
26.37(d) Provision of copies of records pertaining to the determination of a violation of the FFD policy to the subject individual (formerly Appendix A, Subpart C)	1 hour per disclosure 17 per program per year+
26.41(f) Provision to licensee of copy of audit findings and corrective actions by C/V with licensee-approved FFD program (new)	0.5 hour per audit 36 FFD programs+
26.41(g) Exchanges of copies of audit findings and corrective actions among licensees and other entities conducting or relying upon shared audit (formerly 26.80)	0.5 hour per audit 36 FFD programs+
26.75(h)(4) Written notice by licensee to individual that records of unconfirmed positive have not been retained and the temporary administrative action will not be disclosed (formerly 26.24(d)(2)(iv))	0.1 hour per notice* 20 notices per year from 4 respondents*
26.77(d) Notice to NRC of potential FFD problem of NRC employee (formerly 26.27(d))	0.5 hour per notice* No notices anticipated

OMB CLEARANCE ASSUMPTIONS: PART 26 REPORTING REQUIREMENTS (continued)

26.87(d)(3) Posting of sign on designated collection site that access is allowed only for authorized personnel (new requirement)	0.1 hour per posting 40 collection sites
26.119(a) Obtain an written evaluation from a licensed physician of the donor's failure to provide a sufficient specimen (new requirement)	1 hour per evaluation 1 per program per year+
26.119(b) Provide information and instructions from the MRO to the physician performing the evaluation (new requirement)	0.5 hour per evaluation 1 per program per year+
26.129(b) Report indications of tampering with specimens or discrepancies in information on specimen bottles or custody-and-control forms to senior licensee or other entity management no later than 8 hours after the indications are identified	0.5 hour per incident 1 incident per program per year
26.137 (b)(2) and (3) Provide notice to NRC of incorrect results that are false negative results in accordance with 26.219(c)(3)	Covered under 26.219(c)(3)
26.139(a) Reporting initial validity and drug test results to MRO and MRO's staff, FFD program manager, reviewing official, and EAP staff	Covered under 26.219(a) and (b)

OMB CLEARANCE ASSUMPTIONS: PART 26 REPORTING REQUIREMENTS (continued)

26.139(d) Preparation of information required for the annual report to the NRC	Covered under 26.217
26.153(g) Preparation of memorandum by licensee to HHS-certified laboratory explaining why a form other than the current Federal custody-and-control form is used (new requirement)	0.25 hour+ 2 memoranda per year per collection site+
26.159(b) Report by HHS-certified laboratory to licensee or other entity of evidence of tampering or discrepancies in information on specimen bottles and custody-and-control forms (new requirement)	1 hour per report 1 report per program per year
26.161(h) Report by HHS-certified laboratory to NRC and to HHS of new adulterant(s) detected (new requirement)	0.5 hour per report 2 reports per year
26.163(a)(2) Report by HHS-certified laboratory to MRO of results of special analysis down to the confirmatory assay's limit of detection (new requirement)	0.5 hour per report 12 reports per program per year
26.165(a)(4) Written permission by donor for the testing of Bottle B (new requirement)	0.5 hour per permission 12 reports per program per year
26.165(b) Written permission by donor for the retest of a single specimen (new requirement)	0.5 hour per permission 12 reports per program per year

OMB CLEARANCE ASSUMPTIONS: PART 26 REPORTING REQUIREMENTS (continued)

26.165(a)(6) and (c)(4) Report by HHS-certified laboratory to the MRO of results of testing of Bottle B or retest of single specimen (new requirement)	0.5 hour per report of results 24 reports per program per year
26.165(f) Written statement by licensee to individual, following results of testing of Bottle B or retesting of a single specimen that are negative, that the records of the original non-negative test have not been retained and the temporary administrative action will not be disclosed (new requirement)	0.5 hour one time to prepare form letter 0.1 hour per statement sent
26.169 Report by HHS-certified laboratory of test results to licensee's or other entity's MRO within 5 business days after receiving specimen	0.1 hour per report 2,862 reports per program per year+
26.169(k) Submission of statistical summary of urinalysis testing by HHS-certified laboratory to licensee or other entity	0.5 hour per report+ 1 report per program per year+
26.169(k) Submission of quantitative results for all specimens tested by HHS-certified laboratory when requested by the NRC, licensee, or other entity	0.5 hour per report+ 1 report per program per year
26.185(c),(h)(i)(j)(k) Notice by MRO to licensee management of conclusion from review of test results (formerly 26.24(e))	0.25 hour per notice* 60 reports per program per year (increased from 2001 estimate of 15 per year*)

OMB CLEARANCE ASSUMPTIONS: PART 26 REPORTING REQUIREMENTS (continued)

26.185(d)(3) Submission by individual to MRO of information documenting circumstances that prevented individual from contacting the MRO or being contacted by the MRO.	1 hour per submission 5 submissions per program per year
26.185(h)(1) Submission by donor to MRO of medical evidence why the donor produced the specimen for which the laboratory reported a substituted result	1 hour per submission 1 submission per program per year
26.185(i)(1) Submission by donor to MRO of medical evidence that the donor produced the adulterated result through normal human physiology	1 hour per submission 1 submission per program per year
26.187(f) Provide documentation of credentials by SAE when requested by NRC (new requirement)	0.5 hour per request 1 request per year by NRC
26.217 Submit program performance data to NRC (formerly 26.71(d))	40 hours per report.* 1 report per program per year (reduced from 2 under current requirements)
26.217 Report both HHS-approved and more stringent levels if both used (formerly B.2.7(e)(1))	1 hour per report* 2 respondents per year*
26.217 Provide quantitative results for all samples tested when requested by NRC (formerly B.2.7(g)(7))	1 hour per request* 1 respondent per year*
26.219(a), (b) Submit reports of significant FFD events to NRC (formerly 26.73(a))	0.25 hour per report* 1 report per program per year*

OMB CLEARANCE ASSUMPTIONS: PART 26 REPORTING REQUIREMENTS (continued)

26.219(c) Report investigative findings regarding unsatisfactory laboratory performance and corrective actions to NRC (formerly B.2.8(e)(4))	1 hour per report* 2 respondents per year*
26.219(c)(3) Provide immediate notice of false positive administrative error to NRC (formerly B.2.8(e)(5))	1 hour per report* 2 respondents per year*