

Table 1: One Time Recordkeeping							
Section	2011			2014			Change
	Number of Programs	Burden Hours per Program (Annualized)	Total Burden Hours (Annualized)	Number of Programs	Burden Hours per Program (Annualized)	Total Burden Hours (Annualized)	
26.27(a): Prepare FFD policy statement	1.0	107.0	107.0	-	107.0	-	(107.0)
26.27(a): Prepare FFD procedures	1.0	213.0	213.0	-	213.0	-	(213.0)
26.29(a): Prepare FFD training course	1.0	83.0	83.0	-	83.0	-	(83.0)
26.29(b): Prepare FFD exam	1.0	13.3	13.0	-	13.3	-	(13.0)
26.29(b): All current staff take FFD exam	1.0	200.2	200.0	-	200.2	-	(200.0)
26.29(b): FFD staff mgmt grade FFD exam	1.0	200.2	200.0	-	200.2	-	(200.0)
26.29(c)(1): FFD training for current staff	1.0	4,710.7	4,711.0	-	4,710.7	-	(4,711.0)
26.31(b)(1)(v): Prepare behavioral observation procedures for FFD program personnel	Burden shown under 26.27			Burden accounted for under 26.27 (0 programs)			-
26.31(d)(1)(iii): Document additional drugs being tested	1.0	0.3	-	-	0.3	-	-
26.37(a): Confirm files and procedures protect personal information	1.0	2.7	3.0	-	2.7	-	(3.0)
26.37(b): Obtain signed consent for release of information	1.0	98.1	98.0	-	98.1	-	(98.0)
26.39(a) and (b): Prepare procedure for review of determination of FFD violation	1.0	13.3	13.0	-	13.3	-	(13.0)
26.85(a): Prepare and deliver qualification training for urine collectors	1.0	5.3	5.0	-	5.3	-	(5.0)
26.85(b): Prepare and deliver qualification training for alcohol collectors	1.0	5.3	5.0	-	5.3	-	(5.0)
26.127(a): Prepare procedures for handling specimens at licensee testing facility	1.0	13.3	13.0	-	13.3	-	(13.0)
26.127(b): Prepare written chain-of-custody procedures for licensee testing facility	1.0	13.3	13.0	-	13.3	-	(13.0)
26.127(c): Prepare written procedures for assays performed by licensee testing facility	1.0	13.3	13.0	-	13.3	-	(13.0)
26.127(d): Prepare written procedures for instrument and test setup by licensee testing facility	1.0	13.3	13.0	-	13.3	-	(13.0)
26.127(e): Prepare written procedures for remedial actions for systems and tests at licensee testing facility	1.0	13.3	13.0	-	13.3	-	(13.0)
26.137(a): Develop QA/QC program and procedures for licensee testing facility	1.0	13.3	13.0	-	13.3	-	(13.0)
26.155(a)(1), (3), (4), (5); (b),(c), (e), and (f): Confirm that HHS requirements for laboratory personnel qualifications and procedures already in place pursuant to HHS requirements also meet Part 26 requirements	-	2.7	-	-	2.7	-	-
26.157(b), (c), (d), and (e): Confirm that laboratory procedures already in place pursuant to HHS requirements also meet Part 26 requirements	-	2.7	-	-	2.7	-	-
26.159(a), (c), (e), (f): Confirm that specimen security, chain of custody, and preservation procedures already in place pursuant to HHS requirements also meet Part 26 requirements	-	2.7	-	-	2.7	-	-
26.203(a): Prepare fatigue management policy (In addition to 26.27 burden)	1.0	13.3	13.0	2.0	7.3	14.6	1.6
26.203(b): Prepare fatigue management procedures (in addition to 26.27 burden)	1.0	26.6	27.0	2.0	1.7	3.4	(23.6)
26.203(c): Prepare training on fatigue management.	1.0	22.7	23.0	2.0	2.0	4.0	(19.0)
26.205(b): Develop work hour tracking system	1.0	133.3	133.0	2.0	7.7	15.4	(117.6)
26.205(c): Develop individual work scheduling system	1.0	33.3	33.0	2.0	2.0	4.0	(29.0)

<b>Table 1: One Time Recordkeeping</b>							
<b>Section</b>	<b>2011</b>			<b>2014</b>			<b>Change</b>
	<b>Number of Programs</b>	<b>Burden Hours per Program (Annualized)</b>	<b>Total Burden Hours (Annualized)</b>	<b>Number of Programs</b>	<b>Burden Hours per Program (Annualized)</b>	<b>Total Burden Hours (Annualized)</b>	
26.205(d)(7): Implementation of voluntary alternative to minimum days off	22.0	11.7	257.4			-	(257.4)
26.401(b): Prepare Subpart K program plan	1.0	60.0	60.0	-	60.0	-	(60.0)
26.403(a): Prepare written Subpart K FFD policy statement	1.0	107.0	107.0	-	107.0	-	(107.0)
26.403(a): Distribute Subpart K FFD policy statement to all individuals	1.0	5.0	5.0	-	5.0	-	(5.0)
26.403(b): Prepare written Subpart K FFD procedures	1.0	213.0	213.0	-	213.0	-	(213.0)
26.406(a), (b), and (d): Establish a fitness monitoring program	-	26.7	-	-	26.7	-	-
26.406(c): Establish procedures for fitness monitors	-	40.0	-	-	40.0	-	-
26.407: Establish procedures for behavioral observation	-	40.0	-	-	40.0	-	-
26.413: Develop procedures for review of determinations of FFD violations	1.0	120.0	120.0	-	120.0	-	(120.0)
<b>Table 1: Total</b>			<b>6,720.4</b>			<b>41.4</b>	(6,679.0) (6,679.0)

**Table 2: Annual Recordkeeping**

Section	2011			2014			Change
	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours	
26.4: Requires training be provided to persons subject to a drug and alcohol testing program regulated by another Federal agency or State but who are not covered by these training elements of a Part 26 FFD program. Further, these State and Federal entities are required to ensure that the licensee granting authorization is notified of any FFD policy violation.				30.5	2.0	61.0	61.0
26.27(b): Make FFD policy statement available to staff subject to FFD reqs.	31.0	4.0	124.0	28.0	4.0	112.0	(12.0)
26.27(c): Record updates to policy & procedures	31.0	8.0	248.0	28.0	8.0	224.0	(24.0)
26.27(d): Provide policy and procedures for NRC review	31.0	4.0	124.0	28.0	4.0	112.0	(12.0)
26.29(b): Maintain records of FFD exams	31.0	2.0	62.0	28.0	2.0	56.0	(6.0)
26.29(c)(2): Maintain records of refresher FFD training and testing	31.0	2.0	62.0	28.0	2.0	56.0	(6.0)
26.29(d): Record acceptance of FFD training from other licensees' programs	31.0	4.0	124.0	28.0	4.0	112.0	(12.0)
26.31(b)(1)(i): Record results of background checks for FFD personnel	31.0	17.5	542.5	28.0	17.5	490.0	(52.5)
26.31(b)(1)(v): Record results of behavioral observation for FFD program personnel	31.0	80.0	2,480.0	28.0	80.0	2,240.0	(240.0)
26.31(d)(1)(i)(D): Document analysis and certification for unlisted drugs	8.0	4.0	32.0	2.3	4.0	9.2	(22.8)
26.31(d)(1)(ii): Document licensee additions to tested drugs	31.0	8.0	248.0	2.3	8.0	18.4	(229.6)
26.31(d)(3)(iii)(A): Document more stringent cutoff levels	8.0	8.0	64.0	2.0	8.0	16.0	(48.0)
26.31(d)(3)(iii)(C): Document evaluation and certification of more stringent cutoff levels	8.0	8.0	64.0	2.0	8.0	16.0	(48.0)
26.31(d)(6): Document written permission of donor to conduct another analysis or test with specimen	8.0	1.0	8.0	-	1.0	-	(8.0)
26.33: Records of behavioral observations	31.0	400.0	12,400.0	28.0	400.0	11,200.0	(1,200.0)
26.35(a): Employee assistance program records	31.0	16.0	496.0	28.0	16.0	448.0	(48.0)
26.35(c): Maintain record of written waivers of right to privacy from individuals given to EAP	31.0	2.0	62.0	28.0	2.0	56.0	(6.0)
26.35(c): Record of EAP disclosure to FFD mgt.	16.0	1.0	16.0	14.0	1.0	14.0	(2.0)
26.37(b)(1): Record of signed designations of personal representative for FFD matters	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.37(c): Record of disclosures to other licensees	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.37(d): Record of lab results and provide result to individual	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.39(a): Maintain procedures for review of determinations of FFD	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.39(d): Update records to reflect outcome of review of determination of fitness	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.39(e): Record that review procedure provided to individual	31.0	15.5	480.5	-	0.5	-	(480.5)
26.41(a), (b), and (c): Record of audits	Burden shown under 26.41(f)			Burden accounted for under section 26.41(f)			-
26.41(d): Record of review of CV audit results	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.41(f): Document and report audit results	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.41(g): Record that audit results shared with mgmt and with other FFD programs	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.53(a)(2): Record that C/V's informed licensee of the termination of an individual's authorization	2.0	120.0	240.0	1.0	120.0	120.0	(120.0)
26.53(g): Record that CVs and other licensees informed of Part 26 violations	8.0	8.0	64.0	7.0	8.0	56.0	(8.0)
26.53(h): Record that written consent obtained from the subject individual before initiating any actions under Subpart C	31.0	1,411.0	43,741.0	28.0	1,677.0	46,956.0	3,215.0
26.53(i): Record that all individuals applying for authorization informed, in writing, of the causes for denial or termination of authorization	31.0	21.4	663.4	28.0	23.3	652.4	(11.0)
26.55(a)(1) and (a)(2): Record that obtained and reviewed self-disclosure & employment history and completed suitable inquiry	Burden shown under 26.61 and 26.63			Burden accounted for under sections 26.61 and 26.63			-
26.57(a)(1) and (a)(2): Record that obtained and reviewed self-disclosure & employment history & completed suitable inquiry	Burden shown under 26.61 and 26.63			Burden accounted for under sections 26.61 and 26.63			-
26.59(a)(1) and (a)(2): Record that obtained and reviewed self-disclosure & employment history & completed suitable inquiry	Burden shown under 26.61 and 26.63			Burden accounted for under sections 26.61 and 26.63			-
26.59(c)(1): Record that obtained and reviewed self-disclosure	Burden shown under 26.61			Burden accounted for under section 26.61			-
26.61(a): Record of written self-disclosure and employment history	31.0	1,197.0	37,107.0	28.0	1,197.0	33,516.0	(3,591.0)
26.63(a), (c), and (e): Record of suitable inquiry	31.0	1,197.0	37,107.0	28.0	1,197.0	33,516.0	(3,591.0)
26.63(c)(2): File DD 214	31.0	4.0	124.0	28.0	4.0	112.0	(12.0)
26.63(c)(3): Document refusal of past employer to supply employment information	31.0	2.7	83.7	28.0	2.7	75.6	(8.1)
26.63(d) & (e): Maintain documentation of denial or unfavorable termination of authorization from other FFD programs	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.65(d) and (e): Record of reinstatement or administrative withdrawal of authorization	31.0	4.0	124.0	28.0	4.0	112.0	(12.0)
26.65(f): Administrative withdrawal of authorization	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.67: Record of random drug and alcohol testing of persons who have applied for authorization	31.0	4.3	133.3	28.0	5.5	154.0	20.7
26.69(b) and (c)(1): Record of written self-disclosure and employment history	Burden shown under 26.713(a)(1)			Burden accounted for under section 26.713(a)(1)			-
26.69(c)(2): Record that licensee confirmed potentially disqualifying FFD situation resolved	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.69(c)(3): Record that licensee verified that qualified professional indicated individual is fit for duty.	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.69(c)(4): Record of verification that drug/alcohol treatment & testing completed	31.0	3.0	93.0	28.0	3.0	84.0	(9.0)
26.69(c)(5): Record of verification that pre-access drug/alcohol testing completed	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.69(d): Record that reviewing officer's review completed	31.0	24.0	744.0	28.0	24.0	672.0	(72.0)
26.69(e): Record of testing and treatment plans accepted from other FFD programs	31.0	8.0	248.0	28.0	8.0	224.0	(24.0)
26.69(e)(1): Record that information transmitted on testing and treatment plans to other FFD programs	31.0	8.0	248.0	28.0	8.0	224.0	(24.0)
26.75(a), (b), (c), (d), (e), and (g): Record of sanctions for FFD violation	31.0	12.0	372.0	28.0	12.0	336.0	(36.0)
26.75(h): Record additional evidence indicating impairment	31.0	18.0	558.0	28.0	18.0	504.0	(54.0)
26.75(i): Record of positive initial test result and temporary administrative action	31.0	80.0	2,480.0	28.0	80.0	2,240.0	(240.0)
26.75(j): Eliminate from record references to temporary administrative action	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.85(a), (b), & (c): Training collectors	31.0	4.0	124.0	28.0	4.0	112.0	(12.0)
26.85(e): Maintain personnel files	31.0	4.0	124.0	28.0	4.0	112.0	(12.0)
26.87(e)(3) and (f)(1): Signage/security at test sites	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.87(f)(3), (f)(4), and (f)(5): Record of custody-and-control forms	31.0	2.0	62.0	28.0	2.0	56.0	(6.0)
26.89(a): Record of absence of donor reported	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)

**Table 2: Annual Recordkeeping**

Section	2011			2014			Change
	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours	
26.89(b)(1), (b)(2), and (b)(4): Record that ID and consent-to-testing form obtained	31.0	1.5	46.5	28.0	1.5	42.0	(4.5)
26.89(b)(3): Record that FFD program management informed that individual did not present identification	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.89(c): Record of donor's refusal to cooperate in collection procedures	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.91(c)(1), (c)(2), and (c)(3): Record of EBT test results	Burden shown under 26.715(b)(12)			Burden accounted for under section 26.715(b)(2)			-
26.91(e)(4): Record that results cancelled after EBT calibration check failure	8.0	6.0	48.0	-	6.0	-	(48.0)
26.91(e)(5): Prepare record of EBT maintenance	31.0	6.0	186.0	28.0	6.0	168.0	(18.0)
26.93(a)(6): Document alcohol pre-test questions asked and answered	31.0	80.0	2,480.0	28.0	80.0	2,240.0	(240.0)
26.95(b)(5): Record donor identity for initial alcohol breath test	31.0	80.0	2,480.0	28.0	80.0	2,240.0	(240.0)
26.97(b)(2): Record reason for new oral fluid alcohol test	31.0	5.0	155.0	-	5.0	-	(155.0)
26.97(c)(1): Document reason for failure of 2 <sup>nd</sup> collection attempt	31.0	2.5	77.5	-	2.5	-	(77.5)
26.97(d): Record results and alcohol screening device used	31.0	0.3	7.8	-	0.25	-	(7.8)
26.99(b): Record test time of initial test with 0.02% or higher BAC	31.0	0.3	7.8	Burden accounted for under section 26.715(b)(2)			(7.8)
26.101(b)(7): Record time on EBT printout of alcohol test result	31.0	0.3	7.8	-	-	-	(7.8)
26.103(b): Record that FFD mgmt informed of result between 0.01 and 0.02 when donor in work status 3 or more hours	8.0	0.3	2.0	8.0	0.25	2.0	-
26.107(b): Document tampering attempt on CCF form	31.0	0.1	3.1	28.0	0.1	2.8	(0.3)
26.109(b)(3): Record that FFD mgr. or MRO notified of Ashy bladder@ problem	31.0	0.5	15.5	28.0	0.5	14.0	(1.5)
26.109(b)(4): Record that FFD management notified if observed collection requires	31.0	0.3	9.3	28.0	0.3	8.4	(0.9)
26.111(b): Note unusual findings on CCF form	31.0	1.4	43.4	4.0	0.25	1.0	(42.4)
26.111(c): Record that tampering attempts reported to FFD mgr.	31.0	0.3	9.3	28.0	0.3	8.4	(0.9)
26.113(b)(3): Record of CCF forms for both parts of split sample	31.0	0.3	9.3	28.0	0.3	8.4	(0.9)
26.115(b): Record that approval obtained for collection under direct observation from FFD mgr. or MRO	31.0	0.5	15.5	28.0	0.5	14.0	(1.5)
26.115(d): Record of CCF form for directly observed collection	31.0	0.3	9.3	28.0	0.3	8.4	(0.9)
26.115(f)(3): Record of name of observer	31.0	0.3	9.3	28.0	0.3	8.4	(0.9)
26.117(c), (d), and (e): Prepare ID labels and CCF forms for specimen shipment	31.0	60.0	1,860.0	28.0	60.0	1,680.0	(180.0)
26.119(a), (e), and (f): Record that evaluation obtained from MRO or physician evaluating Ashy bladder@ claim	31.0	6.0	186.0	28.0	6.0	168.0	(18.0)
26.119(b): Record that MRO provided information to physician as background for evaluation of Ashy bladder@ claim	31.0	2.0	62.0	28.0	2.0	56.0	(6.0)
26.125(b) and (c): Proficiency and qualifications records of testing facility personnel	31.0	16.0	496.0	7.0	16.0	112.0	(384.0)
26.127(a): Procedures for handling specimens by licensee testing facilities	31.0	40.0	1,240.0	7.0	40.0	280.0	(960.0)
26.127(b): Written chain-of-custody procedures for licensee testing facilities	31.0	40.0	1,240.0	7.0	40.0	280.0	(960.0)
26.127(c): Written procedures for assays performed by licensee testing facilities	31.0	40.0	1,240.0	7.0	40.0	280.0	(960.0)
26.127(d): Written procedures for instrument and device setup by licensee testing facilities	31.0	40.0	1,240.0	7.0	40.0	280.0	(960.0)
26.127(e): Written procedures for remedial actions for systems and testing devices at licensee testing facilities	31.0	40.0	1,240.0	7.0	40.0	280.0	(960.0)
26.129(a): Records associated with limiting access to testing site	31.0	2.5	77.5	7.0	2.5	17.5	(60.0)
26.129(b): Inspect specimen packages, custody control forms, and obtain memorandum from specimen collector	31.0	0.5	15.5	7.0	0.5	3.5	(12.0)
26.129(b)(1): Record of report to senior management of attempts to tamper with specimens in transit	31.0	1.0	31.0	7.0	1.0	7.0	(24.0)
26.129(d): Procedures for tracking CCF of specimens	31.0	80.0	2,480.0	7.0	80.0	560.0	(1,920.0)
26.135(b): Record of donor's written permission for retest second part of split sample	31.0	2.2	68.2	7.0	2.2	15.4	(52.8)
26.137(a): Record of QA/QC program and procedures for licensee testing facility	31.0	4.0	124.0	7.0	4.0	28.0	(96.0)
26.137(b)(1)(ii): Document performance of testing device not on SAMHSA list	2.0	40.0	80.0	2.0	40.0	80.0	-
26.137(b)(1)(iii): Document results of annual test of device not on SAMHSA list	2.0	20.0	40.0	2.0	20.0	40.0	-
26.137(b)(3): Record that 1 in 10 negative specimens submitted for validity screening	31.0	40.0	1,240.0	7.0	40.0	280.0	(960.0)
26.137(e)(7): Document procedures to protect against carryover material	31.0	2.0	62.0	7.0	2.0	14.0	(48.0)
26.137(f)(5): Record finding of testing errors	31.0	24.0	744.0	7.0	24.0	168.0	(576.0)
26.137(h): Label standards and controls	31.0	65.0	2,015.0	7.0	65.0	455.0	(1,560.0)
26.139(d): Record that information prepared for FFD annual report on activities of licensee testing facility	31.0	40.0	1,240.0	7.0	40.0	280.0	(960.0)
26.153(e): Record of inspection of HHS-certified labs	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.153(f): Include specified requirements in contracts with HHS labs	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.153(g): Record of memo to HHS labs explaining use of non-federal CCF form	31.0	0.5	15.5	28.0	0.5	14.0	(1.5)
26.159(b)(1): Record of report of evidence of tampering with specimens in transit to FFD program mgr. of licensee or other entity	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.159(i): Record of written authorization to store specimens other than 1 year	31.0	0.5	15.5	28.0	0.5	14.0	(1.5)
26.163(a)(2): Record that licensee informed of dilute specimen and report confirmatory validity test result to MRO	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.165(b)(1): Record of donor request for the retest of an aliquot of a single specimen or testing of Bottle B of split specimen at a second HHS lab	31.0	1.4	43.4	28.0	1.0	28.0	(15.4)
26.165(b)(2): Record that MRO informed donor of opportunity for re-test of aliquot or test of Bottle B of split sample	31.0	0.5	15.5	28.0	0.5	14.0	(1.5)
26.165(b)(3): Record that donor gave written permission for re-test of aliquot or test of Bottle B of split sample	Burden shown under 26.165(b)(1)			Burden accounted for under section 26.165(b)(1)			-
26.165(b)(4): Record that donor presented documentation for reason for inability to complete timely retest request	31.0	0.2	6.2	6.0	0.2	1.2	(5.0)
26.165(b)(6): Record that results of re-test of aliquot or test of Bottle B provided to MRO and to donor	31.0	3.0	93.0	28.0	3.0	84.0	(9.0)
26.165(c)(4): Record that retesting results provided to MRO	10.0	2.5	25.0	12.0	2.5	30.0	5.0

corrected section reference from (b)(12) to (b)(2)

updated to more accurately reflect that burden is accounted for elsewhere

**Table 2: Annual Recordkeeping**

Section	2011			2014			Change
	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours	
26.165(f)(1): Adjustments to personnel files and written notifications regarding test results, including temporary administrative action	31.0	6.0	186.0	28.0	6.0	168.0	(18.0)
26.165(f)(1)(w) and (f)(2): Written record and notice that records purged of references to temporary administrative action	31.0	8.0	248.0	28.0	8.0	224.0	(24.0)
26.167(f)(3): Record of certification by HHS lab that retesting requested by licensee or other entity has occurred	10.0	1.0	10.0	12.0	1.0	12.0	2.0
26.169(a): Records of reports of test results by HHS lab	Burden covered under 26.169 (c)(1) through (c)(5)			Burden accounted for under sections 26.169 (c)(1) through (c)(5)			-
26.169(c)(1): Records of HHS lab reports of positive, adulterated, substituted, dilute, and invalid test results to the MRO	10.0	80.0	800.0	12.0	80.0	960.0	160.0
26.169(c)(2): Records of HHS lab reports of quantitative test results as requested by MRO	2.0	1.0	2.0	12.0	1.0	12.0	10.0
26.169(c)(2): Records of HHS lab reports of quantitative test results for opiates to MRO	10.0	0.5	5.0	12.0	0.5	6.0	1.0
26.169(c)(3): Records of HHS lab reports of quantitative test results for adulterated or substituted test results	10.0	2.5	25.0	12.0	2.5	30.0	5.0
26.169(c)(4): Record of HHS lab contact with MRO to discuss whether testing by another HHS lab should be done	10.0	2.0	20.0	12.0	2.0	24.0	4.0
26.169(c)(5): Record of HHS lab reports of concentrations exceeding linear range	2.0	1.0	2.0	2.0	1.0	2.0	-
26.169(f): Records of HHS lab transmittals of copies of the CCF form for negative results to the MRO	10.0	125.8	1,258.0	12.0	109.5	1,314.0	56.0
26.169(g): Records of HHS lab transmittals of original of CCF form for positive, adulterated, substituted, dilute or invalid results to the MRO	10.0	42.3	423.0	12.0	44.7	536.4	113.4
26.169(h): Record that HHS lab prepared and submitted annual statistical summary report of analysis testing results	10.0	40.0	400.0	12.0	40.0	480.0	80.0
26.183(a): Documentation of MRO qualifications	31.0	3.5	108.5	28.0	3.5	98.0	(10.5)
26.183(c)(1): MRO review of records for positive, adulterated, substituted, invalid, or, at the licensees or other entities discretion, dilute test results	31.0	26.0	806.0	28.0	19.1	534.8	(271.2)
26.183(d)(1)(i)(D): Record of MRO report of drug test results to licensees designated reviewing official	31.0	26.0	806.0	28.0	19.1	534.8	(271.2)
26.183(d)(2)(i): Record of MRO staff review and reporting of negative test results	31.0	213.0	6,603.0	28.0	292.2	8,181.6	1,578.6
26.183(d)(2)(ii): Record of MRO staff review of CCF forms and forwarding of changes to MRO	31.0	2.6	80.6	28.0	1.9	53.2	(27.4)
26.185(a) Record of MRO review of all positive, adulterated, substituted, dilute, or invalid test results and report to licensee or other entity	31.0	26.0	806.0	28.0	26.0	728.0	(78.0)
26.185(c): Record of MRO discussion of test results with the donor and report to licensee, following discussion with donor, of FFD violation	31.0	26.0	806.0	28.0	26.0	728.0	(78.0)
26.185(d)(1): Documentation that donor declined to discuss test results	31.0	2.0	62.0	28.0	2.0	56.0	(6.0)
26.185(e): Documentation that donor was unavoidably prevented from discussing test results and request to reopen proceeding	31.0	0.3	9.3	28.0	0.3	8.4	(0.9)
26.185(f)(1): Record of MRO consultation with HHS lab to determine whether additional testing needed	31.0	0.5	15.5	28.0	0.5	14.0	(1.5)
26.185(f)(2): Record of MRO contact with donor regarding medical explanation for test result	31.0	0.5	15.5	28.0	0.5	14.0	(1.5)
26.185(h)(1): Record of MRO contact with donor to offer opportunity to provide medical evidence regarding substituted specimen	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.185(h)(1): Record that donor presented medical explanation for substituted result	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.185(h)(2): Record of MRO notification to licensee that no valid medical explanation presented	31.0	2.0	62.0	28.0	2.0	56.0	(6.0)
26.185(h)(3): Record of MRO notification to licensee that valid medical explanation presented	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.185(j)(1): Record of MRO contact with donor to offer opportunity to provide medical evidence regarding adulterated specimen	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.185(j)(1): Record that donor presented medical explanation for adulterated result	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.185(j)(2): Record of MRO notification to licensee that no valid medical explanation presented	31.0	2.0	62.0	28.0	2.0	56.0	(6.0)
26.185(j)(3): Record of MRO notification to licensee that valid medical explanation presented	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.185(j)(3): Record of MRO notification to licensee where evidence of drug abuse	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.185(j)(3): Record of MRO report to licensee that donor has violated FFD policy by use of another individual's prescription medication	31.0	0.5	15.5	28.0	0.5	14.0	(1.5)
26.185(k): Record of MRO report to licensee that no FFD policy violation has occurred	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.185(m): Record of MRO review of inspection and audit reports, quality control data, multiple specimens, and other data to determine if positive, adulterated, substituted, or invalid result is scientifically insufficient for determination of FFD policy violation	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.185(n): Record of MRO report to licensee on result of analysis by second HHS lab	31.0	2.0	62.0	28.0	2.0	56.0	(6.0)
26.185(o): Record of MRO request for quantitation of test results	31.0	0.5	15.5	28.0	0.5	14.0	(1.5)
26.185(o): Record that lab provided quantitation of test results	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.185(p): Record of MRO notice to licensee of determination of FFD policy violation	31.0	8.0	248.0	28.0	8.0	224.0	(24.0)
26.187(d): SAE training requirements	31.0	20.0	620.0	28.0	20.0	560.0	(60.0)
26.187(f): Documentation of SAE credentials and training	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.189(a): Written record of determination of fitness	31.0	80.2	2,486.2	28.0	80.2	2,245.6	(240.6)
26.189(c): Written record of Afor cause@ determination of fitness	31.0	57.5	1,782.5	28.0	16.3	456.4	(1,326.1)
26.189(d): Record of modification of an initial determination of fitness	31.0	1.0	31.0	28.0	1.0	28.0	(3.0)
26.203(a): Prepare fatigue management policy (in addition to 26.27 burden)				2.0	7.3	14.6	14.6
26.203(b): Prepare fatigue management procedures (in addition to 26.27 burden)				2.0	1.7	3.4	3.4
26.203(c): Prepare training on fatigue management.				2.0	2.0	4.0	4.0
26.203(d)(1): Records of work hours	Burden shown under 26.205(c), (d)(1), and (e)(4)			Burden accounted for under 26.205(c), (d)(1), and (e)(4)			-
26.203(d)(2): Records of shift schedules and shift cycles	Burden shown under 26.205(c), (d)(1), and (e)(4)			Burden accounted for under 26.205(c), (d)(1), and (e)(4)			-
26.203(d)(3): Documentation of waivers	Burden shown under 26.207(a)(4)			Burden accounted for under section 26.207(a)(4)			-
26.203(d)(4): Documentation of work hour reviews	Burden shown under 26.205(d)(2), (e)(3) and (e)(4)			Burden accounted for under 26.205(d)(2), (e)(3) and (e)(4)			-
26.203(d)(5): Documentation of fatigue assessment	Burden shown under 26.211(f)			Burden accounted for under section 26.211(f)			-
26.205(b): Record of calculation of work hours	29.0	160.0	4,640.0	23.0	160.0	3,680.0	(960.0)

**Table 2: Annual Recordkeeping**

Section	2011			2014			Change
	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours	
26.205(c): Schedule work hours	29.0	2,080.0	60,320.0	23.0	2,080.0	47,840.0	(12,480.0)
26.205(d)(1): Record of implementation of work hour controls	29.0	50.0	1,450.0	23.0	50.0	1,150.0	(300.0)
26.205(d)(2): Record of adequate rest breaks	29.0	50.0	1,450.0	23.0	50.0	1,150.0	(300.0)
26.205(e)(1) and (2): Record of review of control of work hours twice per calendar year	29.0	40.0	1,160.0	23.0	40.0	920.0	(240.0)
26.205(e)(3): Document methods for reviews	29.0	20.0	580.0	23.0	20.0	460.0	(120.0)
26.205(e)(4): Record and trend problems in regarding work hours	29.0	20.0	580.0	23.0	20.0	460.0	(120.0)
26.207(a)(4): Document basis for waiver	3.0	6.0	18.0	3.0	6.0	18.0	-
26.211(f): Document results of fatigue assessments	29.0	50.0	1,450.0	23.0	50.0	1,150.0	(300.0)
26.405(a): Record of random drug and alcohol testing	1.0	500.0	500.0	2.0	705.0	1,410.0	910.0
26.405(c)(1): Document pre-assignment testing	1.0	2,000.0	2,000.0	2.0	2,338.0	4,676.0	2,676.0
26.405(c)(2) and (c)(3): Document for-cause and post accident testing	1.0	38.0	38.0	2.0	197.0	394.0	356.0
26.405(c)(4): Document follow up testing	1.0	190.0	190.0	2.0	34.5	69.0	(121.0)
26.405(d): Record of testing for specified drugs, adulterants, and alcohol, at Part 26 specified cutoff levels	Burden shown under 26.405(a) - (c)(4)			Burden accounted for under section 26.405(a) - (c)(4)			-
26.405(e): Record of methods to ensure privacy and quality control	1.0	40.0	40.0	2.0	40.0	80.0	40.0
26.405(f): Record that testing conducted at an HHS lab	1.0	40.0	40.0	2.0	40.0	80.0	40.0
26.405(g): Record of MRO review of positive, adulterated, substituted, and invalid drug and validity test results	1.0	50.0	50.0	2.0	50.0	100.0	50.0
26.406(c): Record of fitness monitoring procedures (programs that do not adopt random testing and behavioral observation)	-	80.0	-	-	80.0	-	-
26.411(a): Record of system of files and procedures to protect personal information	1.0	4.0	4.0	2.0	4.0	8.0	4.0
26.411(a): Collection of personal information	1.0	2,000.0	2,000.0	2.0	2,189.0	4,378.0	2,378.0
26.411(b): Record that signed consent forms obtained	1.0	1.5	1.5	2.0	1.5	3.0	1.5
26.413: Document results of review process	1.0	80.0	80.0	2.0	80.0	160.0	80.0
26.415: Document and report audit results	1.0	40.0	40.0	2.0	40.0	80.0	40.0
26.417(a): Retain program records	1.0	20.0	20.0	2.0	20.0	40.0	20.0
26.417(b)(2): Collect FFD program performance data for Subpart K reactor construction site programs	-	-	-	2.0	100.0	200.0	200.0
26.713(a)(1): Retain records of self-disclosure	31.0	80.0	2,480.0	28.0	80.0	2,240.0	(240.0)
26.713(a)(2): Retain records on FFD violations	31.0	80.0	2,480.0	28.0	80.0	2,240.0	(240.0)
26.713(a)(3): Retain records of authorization	31.0	80.0	2,480.0	28.0	80.0	2,240.0	(240.0)
26.713(a)(4): Retain records of FFD determinations	31.0	80.0	2,480.0	28.0	80.0	2,240.0	(240.0)
26.713(b)(1): Retain records of FFD training	31.0	160.0	4,960.0	28.0	160.0	4,480.0	(480.0)
26.713(b)(2): Retain records of audits	31.0	80.0	2,480.0	28.0	80.0	2,240.0	(240.0)
26.713(c): Retain records on 5-year authorization denial and permanent denial	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.713(d): Retain superseded FFD policy	31.0	80.0	2,480.0	28.0	80.0	2,240.0	(240.0)
26.713(e): Retain written agreements for services under Part 26	31.0	16.0	496.0	28.0	16.0	448.0	(48.0)
26.713(f): Retain records of background investigations	31.0	80.0	2,480.0	28.0	80.0	2,240.0	(240.0)
26.713(g): Retain documentation regarding additional drugs tested	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.715(a): Maintain documentation of all aspect of testing process (not otherwise specified in 26.715(b))	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.715(b)(1): Retain personal files	31.0	20.0	620.0	28.0	20.0	560.0	(60.0)
26.715(b)(2): Retain chain-of-custody documents	31.0	240.0	7,440.0	28.0	240.0	6,720.0	(720.0)
26.715(b)(3): Retain quality assurance records	31.0	120.0	3,720.0	28.0	120.0	3,360.0	(360.0)
26.715(b)(4): Retain superseded procedures	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.715(b)(5): Retain all test data	31.0	240.0	7,440.0	28.0	240.0	6,720.0	(720.0)
26.715(b)(6): Retain test reports	31.0	240.0	7,440.0	28.0	240.0	6,720.0	(720.0)
26.715(b)(7): Retain performance test records	31.0	80.0	2,480.0	28.0	80.0	2,240.0	(240.0)
26.715(b)(8): Retain testing error investigation records	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.715(b)(9): Retain certification inspection records	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.715(b)(10): Retain records on preventative maintenance	31.0	40.0	1,240.0	28.0	40.0	1,120.0	(120.0)
26.715(b)(11): Retain records summarizing scientific insufficiency	31.0	20.0	620.0	28.0	20.0	560.0	(60.0)
26.715(b)(12): Retain computer-generated data	31.0	120.0	3,720.0	28.0	120.0	3,360.0	(360.0)
26.715(b)(13): Retain records on visitors	31.0	20.0	620.0	28.0	20.0	560.0	(60.0)
26.715(b)(14): Retain records on EBT maintenance	31.0	20.0	620.0	28.0	20.0	560.0	(60.0)
26.717(a) and (b): Collect FFD performance data for drug and alcohol testing	31.0	200.0	6,200.0	28.0	100.0	2,800.0	(3,400.0)
26.717(a) and (b): Collect FFD performance data for fatigue management programs	-	-	-	23.0	100.0	2,300.0	2,300.0
26.717(c): Analyze drug and alcohol testing program FFD data annually	31.0	80.0	2,480.0	28.0	40.0	1,120.0	(1,360.0)
26.717(c): Analyze fatigue management program data annually	-	-	-	23.0	40.0	920.0	920.0
26.717(d): Drug and alcohol test results leading to termination	2.0	1.0	2.0	1.0	1.0	1.0	(1.0)
26.717(g): Record that required FFD drug and alcohol information shared by C/V with licensee to ensure information is reported completely and is not duplicated in reports submitted to the NRC	2.0	120.0	240.0	1.0	120.0	120.0	(120.0)
26.719(b): Prepare 24-hour event report to submit to the NRC	-	-	-	1.2	1.0	1.2	1.2
26.719(c): Prepare 30-day event report documentation	-	-	-	0.2	40.0	8.0	8.0
26.719(d): Document non-reportable indicators of FFD program weaknesses	31.0	20.0	620.0	30.0	20.0	600.0	(20.0)
26.821(a): Allow NRC to inspect and copy records	31.0	4.0	124.0	30.0	4.0	120.0	(4.0)
26.821(b): Written agreement between C/Vs and licensees to permit authorized NRC representatives to inspect, copy, or take away copies of C/Vs documents, records, and reports	2.0	4.0	8.0	1.0	4.0	4.0	(4.0)
<b>Table 2 Total</b>			<b>351,889.6</b>			<b>314,177.4</b>	<b>(37,712.2)</b>

new entry for 2014 clearance. The requirement existed previously but was not capture in the clearance package.

split original into separate rows for D&A and fatigue  
 split original into separate rows for D&A and fatigue  
 split original into separate rows for D&A and fatigue  
 split original into separate rows for D&A and fatigue

[1] The 2007-2010 clearance estimated 33 FFD programs, which included one mixed-oxide (MOX) fuel fabrication facility. The 2010-2013 clearance estimates 31 FFD programs. The number of FFD programs has been reduced from 33 to 31 because one FFD p

[2] The estimate is based on 991 positive, adulterated, and substituted test results (this includes both alcohol and drug test results) from NRC's CY 2008 FFD program performance data. One-half burden hour is estimated for each test.

[3] The estimate is based on 87,468 pre-assignment tests from NRC's CY 2008 FFD program performance data. One-half burden hour is estimated for each test.

**Table 2: Annual Recordkeeping**

Section	2011			2014			Change
	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours	

- [4] The estimate is based on 664 positive, adulterated, and substituted pre-access test results (this includes both alcohol and drug test results) from NRC's CY 2008 FFD program performance data. One burden hour is estimated for each test result.
- [5] NRCs CY 2008 FFD program performance data reported 54,759 total random drug tests. Of these, this estimate assumes that approximately 0.5% of individuals who have applied for authorization and who have received a pre-access test also will be random.
- [6] The estimate is based on 846 positive, adulterated, and substituted drug test results from NRCs CY 2008 FFD program performance report data. The assumption is that 10% of all donors will request a retest/split specimen test be performed at a second HHS.
- [7] This estimate is based on 6 donors and one burden hour per donor.
- [8] The 2007-2010 clearance estimated that 26 HHS-certified laboratories would provide services under Part 26. The clearance uses updated information obtained from a 2009 industry survey that reported that only 10 laboratories support all Part 26 programs.
- [9] Electronic reporting is allowed by the regulations and assumed for all laboratories. Each laboratory would process a record into their electronic reporting system at 15,095 records per year at a burden-hour estimate of 30 seconds per record.
- [10] NRCs CY 2008 FFD program performance data reported 846 positive, adulterated, and substituted drug test results. It is estimated that an MRO staff spend one burden hour to review each test result and communicate results.
- [11] The estimate assumes that 151,937 tests were conducted in 2008, minus 846 positive, adulterated, and substituted drug tests, equals the total number of negative drug test results reviewed by MROs and MRO staff. Of these, it is estimated that 90% are reviewed.
- [12] NRCs CY 2008 FFD program performance data reported 846 positive, adulterated, and substituted drug test results. It is estimated that MRO staff spend 6 minutes to review each record.
- [13] Based on 1,783 for-cause tests from NRC's CY 2008 FFD program performance report and one burden hour to prepare a record.
- [14] This quantity is based on an estimate of one construction program choosing to conduct random testing (rather than fitness monitoring), 2,000 workers per construction site subject to the FFD program (based on a 2009 NRC site visit and information presented).
- [15] Estimate based on one burden hour per person to document pre-assignment testing for 2,000 workers at the construction site subject to the FFD program.
- [16] Estimate based on one burden hour per person to collect personal information for 2,000 workers at the construction site subject to the FFD program.

**Table 3: Annual Reporting**

Section	2011					2014					Burden change
	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Total Burden Hours	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Total Burden Hours	
26.9: Application to NRC for exemption	2.0	1.0	2.0	16.0	32.0	-	1.0	-	-	-	(32.0)
26.77(c) Report FFD- impaired NRC employee	31.0	-	-	1.0	-	30.0	-	-	1.0	-	-
26.137(b)(3): Report false negative QC test result from LTF	Burden shown under 26.719(c)(3)					Burden accounted for under section 26.719(c)(3)					-
26.139(d): Prepare information from LTF for annual FFD program performance report	Burden shown under 26.717(e) and (f)					Burden accounted for under section 26.717(e) and (f)					-
26.187(f): Provide SAE qualifications documentation to NRC upon request	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	-
26.203(e)(1): Prepare information on waivers of work hour controls for inclusion in FFD program performance report to NRC required by 26.717(e) and (f)	29.0	1.0	29.0	50.0	1,450.0	23.0	1.0	23.0	50.0	1,150.0	(300.0)
26.203(e)(2): Prepare summary of fatigue corrective actions for inclusion in FFD program performance report to NRC required by 26.717(e) and (f)	29.0	1.0	29.0	6.0	174.0	23.0	1.0	23.0	6.0	138.0	(36.0)
26.417(b)(1): Report to NRC by telephone within 24 hours programmatic failures under Subpart K FFD program	1.0	1.0	1.0	4.0	4.0	2.0	1.0	2.0	4.0	8.0	4.0
26.417(b)(2): Prepare annual program performance report for Subpart K FFD program	1.0	1.0	1.0	80.0	80.0	2.0	1.0	2.0	80.0	160.0	80.0
26.717(d): Report termination test results in the annual summary by processing stage	Burden shown under 26.717(e) and (f). NRC's 2008 FFD program performance data indicates 991 positive test results.					Burden accounted for under section 26.717(e) and (f). NRC's 2012 FFD program performance data indicate 1,089 positive, adulterated, substituted, and refusal to test results.					-
26.717(e) and (f): Annual report of FFD program performance fatigue management programs	-	-	-	-	-	62.0	1.0	62.0	8.0	496.0	496.0
26.717(e) and (f): Annual report of FFD program performance for drug and alcohol programs	31.0	1.0	31.0	150.0	4,650.0	65.0	1.0	65.0	60.0	3,900.0	(750.0)
26.719(a): Reports of significant FFD violations, program failures, and errors in testing	Burden reported under 26.719(b) and (c)					Burden accounted for under section 26.719(b) and (c)					-
26.719(b): Report significant FFD violations by phone with in 24 hrs	15.0	1.0	15.0	4.0	60.0	15.0	2.5	37.1	4.0	148.2	88.2
26.719(c)(1): Report results of testing error investigation to NRC with in 30 days	6.0	1.0	6.0	24.0	144.0	6.0	1.0	6.0	24.0	144.0	-
26.719(c)(2): Notify NRC of false positives on blind performance sample with in 24 hrs	1.0	1.0	1.0	4.0	4.0	1.0	1.0	1.0	4.0	4.0	-
26.719(c)(3): Notify NRC of false negative test result on QA check within 24 hrs	4.0	1.0	4.0	4.0	16.0	4.0	1.0	4.0	4.0	16.0	-
<b>Table 3 Total</b>			<b>120.0</b>		<b>6,615.0</b>			<b>226.1</b>		<b>6,165.2</b>	<b>(449.8)</b>

updated text description

split original into separate rows for D&A and fatigue

split original into separate rows for D&A and fatigue

[1] Based on an assumption that programs submit consolidated reports, but that the reports summarize data by site as required by § 26.717(f).

[2] Experience in reviewing licensee reports indicates that most errors reported are associated with false negative results from blind performance sample testing that requires investigation and coordinati



**Table 4: Annual Third-Party Disclosure**

Section	2011			2014			Burden change
	Number of Responses	Burden Hours per Response	Total Annual Burden Hours	Number of Responses	Burden Hours per Response	Total Annual Burden Hours	
26.4: Requires that training be provided to persons subject to a drug and alcohol testing program regulated by another Federal agency or State but who are not covered by these training elements of a Part 26 FFD program. Further, these State and Federal entities are required to ensure that the licensee granting authorization is notified of any FFD policy violation.				14.0	2.0	28.0	28.0
26.31(b)(1)(i): Individuals provide responses to background checks for FFD personnel	87,468.0	1.0	87,468.0	93,890.0	1.0	93,890.0	6,422.0
26.31(d)(6): Donors provide written permission to conduct another analysis or test with specimen	8.0	1.0	8.0	8.0	1.0	8.0	-
26.35(a): Employee assistance program records (independent non-licensure EAP programs)	16.0	32.0	512.0	14.0	32.0	448.0	(64.0)
26.35(c): Individuals give written waiver of right to privacy to EAP	5,476.0	0.3	1,643.0	5,636.0	0.3	1,690.8	47.8
26.35(c): Record of disclosure by independent EAP to FFD mgt.	16.0	1.0	16.0	15.0	1.0	15.0	(1.0)
26.37(b): Individuals provide signed consent for release of information	54,400.0	0.3	16,320.0	1,127.0	0.3	338.1	(15,981.9)
26.37(b)(1): Individuals provide signed designation of personal representative for FFD matters	991.0	1.0	991.0	961.0	1.0	961.0	(30.0)
26.37(d): Record that FFD program personnel provided records to individual	991.0	1.0	991.0	961.0	1.0	961.0	(30.0)
26.53(h): Individuals provide written consent before any actions are initiated under Subpart C	87,468.0	0.3	26,240.0	93,890.0	0.3	28,167.0	1,927.0
26.55(a)(1) and (a)(2): Individual applicants for initial authorization prepare self-disclosure and employment history	Burden shown under 26.61 and 26.63			Burden accounted for under sections 26.61 and 26.63			-
26.57(a)(1) and (a)(2): Individual applicants for authorization update prepare self-disclosure and employment history	Burden shown under 26.61 and 26.63			Burden accounted for under sections 26.61 and 26.63			-
26.59(a)(1) and (a)(2): Individual applicants for authorization reinstatement prepare self-disclosure and employment history	Burden shown under 26.61 and 26.63			Burden accounted for under sections 26.61 and 26.63			-
26.59(c)(1): Individual applicants for authorization reinstatement after period of interruption of no more than 30 days prepare self-disclosure	Burden shown under 26.61			Burden accounted for under section 26.61			-
26.61(a): Individuals prepare written self-disclosure and employment history	87,468.0	1.0	87,468.0	93,890.0	1.0	93,890.0	6,422.0
26.63(a), (c), and (e): Verification from former employers through suitable inquiry that information provided by individual on previous authorization(s) is accurate and complete	87,468.0	0.8	69,974.0	93,890.0	0.8	75,112.0	5,138.0
26.63(c)(2): Receive form DD 214 regarding previous military service	Burden of supplying DD 214 affects DOD			Burden of supplying DD 214 affects DOD			-
26.63(c)(3): Past employer refuses to supply employment information	180.0	0.5	90.0	180.0	0.5	90.0	-
26.67: Records of random drug and alcohol testing of persons who have applied for authorization	274.0	0.5	137.0	335.0	0.5	167.5	30.5
26.69(b) and (c)(1): Applicant provides written self-disclosure and employment history	Burden shown under 26.63			Burden accounted for under section 26.63			-
26.69(c)(2): Record that licensee confirmed potentially disqualifying FFD situation resolved	186.0	2.0	372.0	939.0	2.0	1,878.0	1,506.0
26.85(c): Alternative collectors not employed by licensee provide proof of qualification	22.0	1.0	22.0	22.0	1.0	22.0	-
26.85(e): Maintain personnel files for alternative collectors	22.0	4.0	88.0	22.0	4.0	88.0	-
26.87(f)(3), (f)(4), and (f)(5): Record of information from non-designated (emergency) test site	2.0	1.0	2.0	2.0	1.0	2.0	-
26.89(a): Record that absence of donor reported by non-licensure collection site	2.0	1.0	2.0	2.0	1.0	2.0	-
26.89(b)(3): Record that non-licensure collection site informed FFD program management that individual did not present identification	2.0	1.0	2.0	2.0	1.0	2.0	-
26.89(c): Record that non-licensure collection site reported donor's refusal to cooperate in the collection procedures.	2.0	1.0	2.0	2.0	1.0	2.0	-
26.91(e)(4): Record that results cancelled after EBT calibration check failure (non-licensure collection site)	1.0	1.0	1.0	1.0	1.0	1.0	-
26.91(e)(5): Prepare record of EBT maintenance (non-licensure collection site)	22.0	4.0	88.0	22.0	4.0	88.0	-
26.93(a)(6): Document alcohol pre-test questions asked and answered (non-licensure collection site)	310.0	0.3	93.0	280.0	0.3	84.0	(9.0)
26.95(b)(5): Record donor identity for initial alcohol breath test (non-licensure collection site)	310.0	0.3	93.0	280.0	0.3	84.0	(9.0)
26.97(b)(2): Record reason for new oral fluid alcohol test (non-licensure collection site)	8.0	0.5	4.0	8.0	0.5	4.0	-
26.97(c)(1): Document reason for failure of 2 <sup>nd</sup> collection attempt (non-licensure collection site)	1.0	1.0	1.0	1.0	1.0	1.0	-
26.97(d): Record results and alcohol screening device used (non-licensure collection site)	8.0	0.3	2.0	8.0	0.3	2.4	0.4
26.99(b): Record test time of initial test with 0.02% or higher BAC (non-licensure collection site)	1.0	0.3	-	1.0	0.3	0.3	0.3
26.101(b)(7): Indicate time on EBT printout of confirmatory alcohol test result (non-licensure collection site)	1.0	0.3	-	1.0	0.3	0.3	0.3
26.103(b): Non-licensure collector informs FFD mgmt of result between 0.01 and 0.02 when donor in work status 3 or more hours	-	0.5	-	-	0.5	-	-
26.107(b): Document tampering attempt on CCF form (non-licensure collection site)	-	1.0	-	-	1.0	-	-
26.109(b)(3): Record that non-licensure collector notified FFD management or MRO notified of Ashy bladder@ problem	-	0.5	-	-	0.5	-	-
26.109(b)(4): Record that non-licensure collector notified FFD management if observed collection required	-	0.3	-	-	0.3	-	-
26.111(b): Non-licensure collector notes unusual findings on CCF form	2.0	0.5	1.0	2.0	0.5	1.0	-
26.111(c): Record that non-licensure collector notified FFD mgr. of tampering attempts	-	0.4	-	-	0.4	-	-
26.113(b)(3): Record of CCF forms for both parts of split urine sample (non-licensure collection site)	-	0.3	-	-	0.3	-	-
26.115(b): Record that approval obtained for collection under direct observation from FFD mgr. or MRO (non-licensure collection site)	-	0.3	-	-	0.3	-	-
26.115(d): Record of CCF form for directly observed collection (non-licensure collection site)	-	0.3	-	-	0.3	-	-
26.115(f)(3): Record of name of observer (non-licensure collection site)	-	0.3	-	-	0.3	-	-
26.117(c), (d), and (e): Prepare ID labels and CCF forms for specimen shipment (non-licensure collection site)	310.0	0.3	93.0	280.0	0.3	84.0	(9.0)
26.119(a), (e), and (f): Record that evaluation obtained from MRO or physician evaluating Ashy bladder@ claim (non-licensure collection site)	-	6.0	-	-	6.0	-	-

**Table 4: Annual Third-Party Disclosure**

Section	2011			2014			Burden change
	Number of Responses	Burden Hours per Response	Total Annual Burden Hours	Number of Responses	Burden Hours per Response	Total Annual Burden Hours	
26.119(b): MRO provides information to physician as background for evaluation of Ashy bladder@ claim	-	2.0	-	-	2.0	-	-
26.129(b): Non-licensure specimen collector prepares memorandum to licensee testing facility personnel documenting investigation of discrepancies between bottles and CCF forms	-	1.0	-	-	1.0	-	-
26.135(b): Donor prepares written permission for retest second part of split sample	1.0	0.5	1.0	1.0	0.5	0.5	(0.5)
26.137(b)(3): Submit 1 in 10 negative specimens for validity screening to HHS lab	-	40.0	-	-	40.0	-	-
26.153(g): Supply memo to HHS labs explaining use of non-federal CCF form	2.0	0.5	1.0	2.0	0.5	1.0	-
26.155(a)(1): Document qualifications for lab mgr of HHS-certified lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			-
26.155(a)(3): Lab manager documents training of lab personnel	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.155(a)(4): Lab manager reviews and signs lab procedures	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.155(a)(5): Lab manager maintains QA program	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.155(b): Certifying scientist to certify test results from HHS lab	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.155(c): Supervise technical analysts at HHS lab	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.155(e): Continuing education for staff at HHS lab	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.155(f): Lab personnel records	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.157(a): Written procedures for accession, receipt, shipment, and testing of urine specimens at the HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			-
26.157(b): Written chain-of-custody procedures for HHS lab	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.157(c): Written procedures manual for each assay performed by HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			-
26.157(d): Written procedures for device set-up and operation	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.157(e): Written procedures for remedial actions to address systems and instrument errors	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			-
26.159(a): Documented restriction to access to HHS lab	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.159(c), (d), and (e): Use and storage of CCF forms	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.159(f): Use of CCF form when shipping specimen to another HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			-
26.165(b)(1): Donor requests aliquot or split specimen to be tested by a second HHS lab	1.0	1.0	1.0	1.0	1.0	1.0	-
26.165(b)(2): Record that non-licensure MRO informed donor of opportunity for re-test of aliquot or test of Bottle B of split sample	1.0	0.3	0.3	1.0	0.3	0.3	-
26.165(b)(3): Written permission by donor for re-test of aliquot or test of Bottle B of split sample	1.0	1.0	1.0	1.0	1.0	1.0	-
26.165(b)(4): Donor presents documentation for reason unable to complete timely retest request	-	1.0	-	-	1.0	-	-
26.165(b)(6): HHS lab provides results of re-test of aliquot or test of Bottle B to MRO and to donor	1.0	0.5	0.5	1.0	0.5	0.5	-
26.167(a): Document quality assurance program of HHS lab	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.167(c)(2)(i): Refractometer at the HHS lab must display specific gravity to 4 decimals and be interfaced with laboratory information management system or computer and/or document result by hard copy or electronic display	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			-
26.167(f)(3): Certification by HHS lab that retesting requested by licensee or other entity has occurred	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.167(h): Labeling of standards and controls	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements			-
26.168(a): Certification of contents of blind performance test samples submitted to HHS lab	Burden covered by HHS lab certification requirements			Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			-
26.168(h)(2): Ensure supplier provides expiration date for test sample	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			-
26.168(i)(2): Use CCF form, place fictional initials on specimen labels, and indicate blind performance test samples	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			-
26.169(a): Reports of test results by HHS lab	Burden covered under 26.169(c)(1) through (c)(5)			Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158			-
26.169(c)(1): HHS lab record of reports of positive, adulterated, substituted, dilute, and invalid test results to the MRO	846.0	0.3	211.5	686.0	0.3	171.5	(40.0)
26.169(c)(2): HHS lab record of quantitative test results as requested by MRO	5.0	1.0	5.0	5.0	1.0	5.0	-
26.169(c)(2): HHS lab record of quantitative test results for opiates to MRO	16.0	1.0	16.0	16.0	1.0	16.0	-
26.169(c)(3): HHS lab record of quantitative test results for adulterated or substituted test results	51.0	1.0	51.0	5.0	1.0	5.0	(46.0)
26.169(c)(4): HHS lab record of contact with MRO to discuss whether testing by another HHS lab should be done	10.0	0.5	5.0	10.0	0.5	5.0	-
26.169(f): HHS lab transmits copy of the CCF form for negative results to the MRO	Electronic transmission			Electronic transmission			-
26.169(g): HHS lab transmits original of CCF form for positive, adulterated, substituted, dilute or invalid results to the MRO	846.0	0.5	423.0	686.0	0.5	343.0	(80.0)
26.169(h): HHS lab prepares and submits annual statistical summary report of urinalysis testing results	10.0	40.0	400.0	10.0	40.0	400.0	-

**Table 4: Annual Third-Party Disclosure**

Section	2011			2014			Burden change
	Number of Responses	Burden Hours per Response	Total Annual Burden Hours	Number of Responses	Burden Hours per Response	Total Annual Burden Hours	
26.183(a): Documentation of MRO qualifications	23.0	1.0	23.0	28.0	1.0	28.0	5.0
26.183(c)(1): MRO review of records for positive, adulterated, substituted, invalid, or, at the licensee's or other entity's discretion, dilute test results	Burden covered by 26.185(a)			Burden accounted for under section 26.185(a)			-
26.183(d)(2)(i): Record of MRO staff review and reporting of negative test results	101,986.0	0.1	5,099.3	16,383.0	0.1	819.2	(4,280.2)
26.183(d)(2)(ii): Record of MRO staff review of CCF forms and forward changes to MRO	635.0	0.1	63.5	54.0	0.1	5.4	(58.1)
26.185(a) Record of MRO review of all positive, adulterated, substituted, or invalid test results and report to licensee or other entity	635.0	1.0	635.0	635.0	1.0	635.0	-
26.185(c): Record of MRO discussion of test results with the donor and record of report to licensee, following discussion with donor, of FFD violation	635.0	1.0	635.0	635.0	1.0	635.0	-
26.185(d)(1): Documentation that donor declined to discuss test results	81.0	1.0	81.0	81.0	1.0	81.0	-
26.185(e): Documentation that donor was unavoidably prevented from discussing test results and request to reopen proceeding	8.0	1.0	8.0	8.0	1.0	8.0	-
26.185(f)(1): MRO consultation with HHS lab to determine whether additional testing needed	Burden covered by 26.185(c)			Burden accounted for under section 26.185(c)			-
26.185(f)(2): MRO contact with donor regarding medical explanation for test result	Burden covered by 26.185(c)			Burden accounted for under section 26.185(c)			-
26.185(h)(1): MRO contact with donor to provide medical evidence regarding substituted specimen	Burden covered by 26.185(c)			Burden accounted for under section 26.185(c)			-
26.185(h)(2): MRO notification to licensee that no valid medical explanation presented	Burden covered by 26.185(c)			Burden accounted for under section 26.185(c)			-
26.185(h)(3): MRO notification to licensee that valid medical explanation presented	Burden covered by 26.185(c)			Burden accounted for under section 26.185(c)			-
26.185(i)(1): MRO contact with donor to provide medical evidence regarding adulterated specimen	Burden covered by 26.185(c)			Burden accounted for under section 26.185(c)			-
26.185(i)(2): MRO notification to licensee that no valid medical explanation presented	Burden covered by 26.185(c)			Burden accounted for under section 26.185(c)			-
26.185(i)(3): MRO notification to licensee that valid medical explanation presented	Burden covered by 26.185(c)			Burden accounted for under section 26.185(c)			-
26.185(j)(3): MRO notification to licensee where evidence of drug abuse	Burden covered by 26.185(c)			Burden accounted for under section 26.185(c)			-
26.185(j)(3): MRO report to licensee that donor has violated FFD policy by use of another individual's prescription medication	Burden covered by 26.185(c)			Burden accounted for under section 26.185(c)			-
26.185(k): MRO report to licensee that no FFD policy violation has occurred	24.0	1.0	24.0	24.0	1.0	24.0	-
26.185(m): MRO review of inspection and audit reports, quality control data, multiple specimens, and other data to determine if positive, adulterated, substituted, or invalid result is scientifically insufficient for determination of FFD policy violation	24.0	1.0	24.0	24.0	1.0	24.0	-
26.185(n): Record of MRO report to licensee on result of analysis by second laboratory	64.0	1.0	64.0	54.0	1.0	54.0	(10.0)
26.185(o): Record of MRO request for quantitation of test results	8.0	0.5	4.0	8.0	0.5	4.0	-
26.185(o): Lab provides quantitation of test results	8.0	1.0	8.0	8.0	1.0	8.0	-
26.185(p): MRO notice to licensee of determination of FFD policy violation	Burden covered by 26.185(c)			Burden accounted for under section 26.185(c)			-
26.187(d): SAE training requirements	24.0	20.0	480.0	24.0	20.0	480.0	-
26.187(f): Documentation of SAE credentials and training	24.0	1.0	24.0	24.0	1.0	24.0	-
26.189(a): Written record of determination of fitness	245.0	0.5	122.5	69.0	1.0	69.0	(53.5)
26.189(c): Written record of a For-cause determination of fitness	76.0	1.0	76.0	6.9	1.0	6.9	(69.1)
26.189(d): Modification of an initial determination of fitness based on information from other sources	24.0	1.0	24.0	24.0	1.0	24.0	-
26.209(a): Persons must self declare whether they are fatigued				23.0	0.3	6.9	6.9
26.405(g): MRO report of positive, adulterated, substituted, and invalid drug test results	-	1.0	-	90.0	1.0	90.0	90.0
26.411(b): Obtain signed consent form	2,000.0	0.3	600.0	4,675.0	0.3	1,402.5	802.5
26.719(c): Respond to a request for information associated with a 30-day event report due to a LTF or HHS-certified laboratory testing error				6.0	8.0	48.0	48.0
26.821(b): Written agreement between CVs and licensees to permit authorized NRC representatives to inspect, copy, or take away copies of CV's documents, records, and reports	5.0	4.0	20.0	5.0	4.0	20.0	-
<b>Table 4 Total</b>	<b>521,756.0</b>		<b>301,855.6</b>	<b>410,999.9</b>		<b>303,559.1</b>	<b>1,703.5</b>

1,703.5

**Reason for Change in Burden or Cost Table**

Table	Description	Clearance Period		Difference between the 2011-2014 and 2014-2017 Collections (hours)
		2011-2014 (hours)	2014-2017 (hours)	
1	One-Time Recordkeeping	6,720.4	41.4	-6,679.0
2	Recordkeeping	351,889.6	314,177.4	-37,712.2
3	Reporting	6,615.0	6,165.2	-449.8
4	Third Party Disclosure	301,855.6	303,559.1	1,703.5
<b>TOTAL</b>		<b>667,080.6</b>	<b>623,943.1</b>	<b>-43,137.5</b>

## Estimate of Industry Burden and Costs

Table	Description	Responses	Burden Hours	Cost at \$272/hr
1	One-Time Recordkeeping*	-	41.4	\$ 11,261
2	Recordkeeping	65.0	314,177.4	\$ 85,456,253
3	Reporting	226.1	6,165.2	\$ 1,676,934
4	Third Party Disclosure	410,999.9	303,559.1	\$ 82,568,062
<b>TOTAL</b>		<b>411,291.0</b>	<b>623,943.1</b>	<b>\$ 169,712,510</b>

\*All one-time recordkeepers are also annual recordkeepers and are included in the recordke

314,218.8

eping responses total.