

OMB INFORMATION COLLECTION
SUPPORTING STATEMENT

**Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and “Lookback”
0910-0116**

O116 Package
0460 Package

1. Estimates of Annualized Burden Hours and Costs

The total annual estimated burden imposed by this collection of information is 426,913 hours.

Table 1. – Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
606.170(a)	353 ⁴	1.20	424	0.5	212
606.170(b) ¹	100	1	100	20	2,000
610.40(c)(1)(ii)	2,081	5.77	12,000	0.08	960
610.40(g)(2)	1	1	1	1	1
610.40(h)(2)(ii)(A)	1	1	1	1	1
610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)	40	12	480	0.2	96
610.40(h)(2)(vi)	2,081	8.65	18,000	0.08	1,440
610.42(a)	1	1	1	1	1
610.46(a)(1)(ii)(B)	2,000	5.25	10,500	0.17	1,785
610.46(a)(3)	2,000	5.25	10,500	0.17	1,785
610.47(b)(3)	4,980	0.41	2,050	1.0	2,050
610.47(a)(1)(ii)(B)	2,000	11.70	23,400	0.17	3,978
610.47(a)(3)	2,000	11.70	23,400	0.17	3,978
610.47(b)(3)	4,980	0.41	2,050	1.0	2,050
630.6(a) ²	667	644.68	430,000	0.08	34,400
630.6(a) ³	104	43.27	4,500	1.5	6,750
630.6(d)(1)	100	30	3,000	1	3,000
Total					64,487

TABLE 2. -Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.100(b) ¹	353 ³	1	353	24	8,472
606.100(c)	353 ³	10	3,530	1	3,530
606.110(a) ²	35 ⁴	1	35	0.5	18
606.151(e)	353 ³	12	4,236	0.083	352
606.160 ³	353 ³	793.20	280,000	0.75	210,000
606.160(b)(1)(viii)					
HIV consignee notification	2,000 4,980	10.50 4.21	21,000 21,000	.17 .17	3,570 3,570
HCV consignee notification	2,000 4,980	23.40 9.4	46,800 46,800	.17 .17	7,956 7,956
HIV recipient notification	4,980	0.35	1,755	.17	298
HCV recipient notification	4,980	0.41	2,050	.17	349
606.160(b)(1)(ix)	2,081	840.94	1,750,000	0.05	87,500
606.160(b)(1)(xi)	2,000	3.375	6,750	0.05	338
606.165	353 ³	793.20	280,000	0.083	23,240
606.170(a)	353 ³	12	4,236	1.00	4,236
610.40(g)(1)	2,081	1	2,081	0.5	1,041
Total					362,426