Biological Product and HCT/P Deviation Reports –

Annual Summary for Fiscal Year 2016

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I. Summary:

FDA requires reporting of certain deviations and unexpected events in manufacturing in accordance with 21 CFR 600.14, 606.171 or 1271.350(b). The following manufacturers, who had control over the product when a deviation or unexpected event occurred are required to submit Biological Product Deviation (BPD) reports to the Center for Biologics Evaluation and Research (CBER), if the safety, purity, or potency of a distributed product may be affected:

- Manufacturers of licensed biological products other than blood and blood components (licensed non-blood) who hold the biological product license [21 CFR 600.14];
- Licensed manufacturers of blood and blood components, including Source Plasma [21 CFR 606.171];
- Unlicensed registered blood establishments [21 CFR 606.171]; and
- Transfusion services [21 CFR 606.171].

The following are required to submit deviation reports to CBER, if the deviation or unexpected event involving a distributed product is related to a Core Current Good Tissue Practice requirement [21 CFR 1271.150(b)] and related to the prevention of communicable disease transmission or HCT/P contamination:

- Manufacturers of nonreproductive Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) regulated by FDA solely under section 361 of the Public Health Service Act and 21 CFR Part 1271 [21 CFR 1271.350(b)],

Detailed information concerning deviation reporting, including guidance documents on BPD reporting for blood and plasma establishments (Ref. 1) and licensed manufacturers of biological products other than blood and blood components (Ref. 2), is available at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/default.htm. A draft guidance for deviation reporting for 361 HCT/Ps (Ref. 3) was published in December 2015, and may be found at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/default.htm

This annual summary report provides an overview of the reports we received during the fiscal year, including detailed information regarding the number and types of deviation reports received. We provide combined data received over the last three fiscal years in an effort to compare data and highlight changes. Throughout the analysis, we report numbers from past reports, calculate changes, or consider aggregate counts from multiple BPD codes. These data may or may not be included in accompanying tables. Detailed counts for all BPD codes can be found in the attachments and past summary reports are available at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129757.htm.

Unfortunately, our system does not collect the necessary denominator data to calculate genuine rates when evaluating possible trends. Some perspective is gained by knowing that in calendar year 2011, an estimated 17.7 million whole blood and red blood cells products were collected and there were 21 million transfusions in the United States. [1] In calendar year 2013, an estimated 14.2 million whole blood and red blood cells products were collected and there were 19 million transfusions in the United States. [2] In addition, there were 29.4 million Source Plasma donations in 2013, 32.6 million Source Plasma donations in 2014, and 35.5 million Source Plasma donations in 2015 made in the U.S.[3]

During fiscal year 2016 (hereafter FY16), October 1, 2015, through September 30, 2016, CBER's Office of Compliance and Biologics Quality/Division of Inspections and Surveillance entered 51,229 deviation reports into the BPD database (Table 1):

- We received more than 51,229 reports, but this summary does not capture data for reports that did not meet the reporting threshold. We notified the reporter when a report was not required.
- There was a 10.0% (4,642 reports) increase in the number of reports we received in FY16 compared to FY15 (Table 2).
    - Blood and Source Plasma establishments submitted 4,546 more reports in FY16 compared to FY15 (Table 2).
        - Licensed blood establishments submitted four more reports in FY16.
        - Unlicensed registered blood establishments submitted 482 more reports in FY16.
        - Transfusion services submitted 130 more reports in FY16.
        - Source Plasma establishments submitted 3,930 more reports in FY16.
    - Manufacturers of licensed biological products other than blood and blood components submitted 93 more reports in FY16 compared to FY15 (Table 2).
        - Allergenic manufacturers submitted seven more reports in FY16
        - Blood derivative manufacturers submitted 11 more reports in FY16.
        - Licensed in-vitro diagnostic manufacturers submitted 33 more reports in FY16.
        - Vaccine manufacturers submitted 42 more reports in FY16.
        - Licensed HCT/P manufacturers (351 HCT/P) submitted the same number of reports in FY16 as in FY15.

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[1] Report of the US Department of Health and Human Services. The 2011 national blood collection and utilization survey report. Washington, DC: US Department of Health and Human Services, Office of the Assistant Secretary of Health. http://www.hhs.gov/ash/bloodsafety/nbcus/index.html

[2] Chung, K.-W., Basavaraju, S. V., Mu, Y., van Santen, K. L., Haass, K. A., Henry, R., Berger, J. and Kuehnert, M. J. (2016), Declining blood collection and utilization in the United States. Transfusion. doi: 10.1111/trf.13644

[3] Plasma Protein Therapeutics Association at http://pptaglobal.org/plasma/plasma-collection

    - 361 HCT/P manufacturers submitted three more reports in FY16 compared to FY15 (Table 2).
        - Cellular HCT/P manufacturers submitted the same number of reports in FY16 as in FY15.
        - Tissue HCT/P manufacturers submitted three more reports in FY16.

- The total number of reporting establishments increased from 1,907 in FY15 to 1,950 in FY16 (Table 2).
    - Compared to FY15, there were seven more licensed blood establishments, five more unlicensed blood establishments, 25 fewer transfusion services and 44 more Source Plasma establishments reporting in FY16.
    - Compared to FY15, there were three more allergenic manufacturers, five more blood derivative manufacturers, five more in-vitro diagnostic manufacturer, and the same number of vaccine and 351 HCT/P manufacturers reporting in FY16.
    - Compared to FY15, there were five more 361 HCT/P manufacturers reporting in FY16.

Each firm responsible for reporting biological product deviations should use this information in evaluating their own deviation management program.

You may submit questions concerning this summary to:
U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

You may also contact us by email at bp_deviations@fda.hhs.gov, hctp_deviations@fda.hhs.gov, or sharon.ocallaghan@fda.hhs.gov (Sharon O'Callaghan).

Total Deviation Reports
FY16

Table 1

Establishment Type	Number Of Reporting Establishments	Total Reports Received	*Potential* Recalls[3]	
			#Reports	% *Potential* Recall
Blood/Plasma Manufacturers				
Licensed Blood Establishments	226(98*)	18,664	467	2.5%
Unlicensed Blood Establishments[1]	393	3,575	23	0.6%
Transfusion Services[2]	644	1,956	0	0.0%
Source Plasma Establishments	506(20*)	26,124	96	0.4%
Sub-Total	*1,769*	*50,319*	*586*	*1.2%*
Licensed Non-Blood Manufacturers				
Allergenic	6(6*)	89	4	4.5%
Blood Derivative	30(23*)	134	5	3.7%
In Vitro Diagnostic	14(14*)	144	0	0.0%
Vaccine	24(18*)	265	0	0.0%
351 HCT/P	5(4*)	19	0	0.0%
Sub-Total	*79(65*)*	*651*	*9*	*1.4%*
361 HCT/P Manufacturers				
Cellular HCT/P	55	134	0	0.0%
Tissue HCT/P	47	125	17	13.6%
Sub-Total	*102*	*259*	*17*	*6.6%*
Total	**1,950**	**51,229**	**612**	**1.2%**

[1]Unlicensed Blood Establishments – unlicensed blood establishments that perform manufacturing of blood and blood components are required to register with FDA.

[2]Transfusion Services – blood banks that perform limited blood and blood component manufacturing (e.g. pooling, thawing, compatibility testing), may or may not register with FDA.

[3]Percent of Potential Recalls calculated for each establishment type (#potential recalls/#total reports)

*****Number of license holders; one or more establishments operate under one biologics license.

Total Deviation Reports
FY14 – FY16

Table 2

Establishment Type	Number Of Reporting Establishments			Total Reports Received			*Potential* Recalls		
Blood/Plasma Manufacturers	**FY14**	**FY15**	**FY16**	**FY14**	**FY15**	**FY16**	**FY14**	**FY15**	**FY16**
Licensed Blood Establishments	210(97*)	219(96*)	226(98*)	21,433	18,660	18,664	503	486	467
Unlicensed Blood Establishments[1]	372	388	393	3,481	3,093	3,575	21	14	23
Transfusion Services[2]	649	669	644	1,735	1,826	1,956	0	2	0
Source Plasma Establishments	423(21*)	462(21*)	506(20*)	23,050	22,194	26,124	80	67	96
Sub-Total	*1,654*	*1,738*	*1,769*	*49,699*	*45,773*	*50,319*	*604*	*569*	*586*
Licensed Non-Blood Manufacturers									
Allergenic	8(8*)	9(9*)	6(6*)	87	82	89	3	4	4
Blood Derivative	26(21*)	25(20*)	30(23*)	109	123	134	1	1	5
In Vitro Diagnostic	11(11*)	9(9*)	14(14*)	128	111	144	7	4	0
Vaccine	24(18*)	24(18*)	24(18*)	247	223	265	3	2	0
351 HCT/P	4(2*)	5(3*)	5(4*)	27	19	19	1	0	0
Sub-Total	*73(60*)*	*72(59*)*	*79(65*)*	*598*	*558*	*651*	*15*	*11*	*9*
361 HCT/P Manufacturers									
Cellular HCT/P	52	47	55	146	134	134	0	0	0
Tissue HCT/P	53	50	47	155	122	125	28	25	17
Sub-Total	*105*	*97*	*102*	*301*	*256*	*259*	*28*	*25*	*17*
Total	**1,832**	**1,907**	**1,950**	**50,598**	**46,587**	**51,229**	**647**	**605**	**612**

[1]Unlicensed Blood Establishments – unlicensed blood establishments that perform manufacturing of blood and blood components are required to register with FDA.

[2]Transfusion Services – blood banks that perform limited blood and blood component manufacturing (e.g. pooling, thawing, compatibility testing), may or may not register with FDA.

*Number of license holders; one or more establishments operate under one biologics license.

Blood & Source Plasma BPD Reports by Manufacturing System
FY14 – FY16

Table 3

Manufacturing System	**FY14**		**FY15**		**FY16**	
Donor Eligibility	37,758	76.0%	34,098	74.5%	37,295	74.1%
Post Donation Information	*36,072*	*72.6%*	*32,729*	*71.5%*	*35,618*	*70.8%*
Donor Screening	*1,303*	*2.6%*	*1,328*	*2.9%*	*1,628*	*3.2%*
Donor Deferral	*383*	*0.8%*	*41*	*0.1%*	*49*	*0.1%*
QC & Distribution	4,460	9.0%	4,422	9.7%	5,140	10.2%
Miscellaneous	3,749	7.5%	3,680	8.0%	4,179	8.3%
Labeling	1,675	3.4%	1,638	3.6%	1,717	3.4%
Collection	953	1.9%	928	2.0%	903	1.8%
Laboratory Testing	829	1.7%	802	1.8%	841	1.7%
Routine Testing	*817*	*1.6%*	*794*	*1.7%*	*827*	*1.6%*
Viral Testing	*12*	*<0.1%*	*8*	*<0.1%*	*14*	*<0.1%*
Component Preparation	275	0.6%	205	0.4%	244	0.5%
Total	**49,699**	**100.0%**	**45,773**	**100.0%**	**50,319**	**100%**

Blood & Plasma BPD Reports by Manufacturing System
FY14 – FY16

Table 4

Manufacturing System	Licensed Blood Establishments			Unlicensed Blood Establishments		
	FY14	FY15	FY16	FY14	FY15	FY16
DE-Post Donation Information	15,699	13,474	12,978	366	313	326
QC & Distribution	1,190	1,122	1,215	1,860	1,660	2,005
Miscellaneous	1,213	1,143	1,370	13	17	14
Labeling	506	482	435	772	727	807
DE-Donor Screening	1,113	1,158	1,390	45	25	55
Blood Collection	879	868	877	72	56	21
LT-Routine Testing	228	232	193	297	236	270
Component Preparation	220	150	169	51	52	69
DE-Donor Deferral	375	25	24	3	5	7
LT-Viral Testing	10	6	13	2	2	1
Total	**21,433**	**18,660**	**18,664**	**3,481**	**3,093**	**3,575**

DE-Donor Eligibility
LT-Laboratory Testing

Table 4 (continued)

Manufacturing System	Transfusion Services			Source Plasma Establishments			Total		
	FY14	FY15	FY16	FY14	FY15	FY16	FY14	FY15	FY16
DE-Post Donation Information	NA	NA	NA	20,007	18,942	22,314	36,072	32,729	35,618
QC & Distribution	1,043	1,073	1,147	367	567	773	4,460	4,422	5,140
Miscellaneous	NA	NA	NA	2,523	2,520	2,795	3,749	3,680	4,179
Labeling	397	424	440	0	5	35	1,675	1,638	1,717
DE-Donor Screening	NA	NA	NA	145	145	183	1,303	1,328	1,628
Blood Collection	NA	NA	NA	2	4	5	953	928	903
LT-Routine Testing	292	326	364	0	0	0	817	794	827
Component Preparation	3	3	5	1	0	1	275	205	244
DE-Donor Deferral	NA	NA	NA	5	11	18	383	41	49
LT-Viral Testing	NA	NA	NA	0	0	0	12	8	14
Total	**1,735**	**1,826**	**1,956**	**23,050**	**22,194**	**26,124**	**49,699**	**45,773**	**50,319**

DE-Donor Eligibility
LT-Laboratory Testing
NA-Not applicable; manufacturing not performed in transfusion service

Licensed Non-Blood Deviation Reports by Manufacturing System FY14 – FY16

Table 5

Manufacturing System	Allergenic			Blood Derivative			In Vitro Diagnostic		
	FY14	FY15	FY16	FY14	FY15	FY16	FY14	FY15	FY16
Product Specifications	81	69	71	33	35	57	76	66	97
Quality Control & Distribution	0	0	1	14	22	18	19	20	29
Labeling	5	6	11	8	2	11	12	14	4
Process Controls	0	2	2	31	27	18	12	3	4
Testing	1	4	4	14	23	13	2	3	6
Miscellaneous	0	0	0	1	7	2	1	1	1
Incoming Material	0	1	0	8	7	15	6	4	3
Total	**87**	**82**	**89**	**109**	**123**	**134**	**128**	**111**	**144**

Table 5 (continued)

Manufacturing System	Vaccine			351 HCT/P			Total		
	FY14	FY15	FY16	FY14	FY15	FY16	FY14	FY15	FY16
Product Specifications	84	74	103	8	8	2	282	252	330
Quality Control & Distribution	48	30	46	1	0	0	82	72	94
Labeling	29	22	17	15	8	14	69	52	57
Process Controls	14	20	40	0	1	0	57	53	64
Testing	36	43	21	3	2	3	56	75	47
Miscellaneous	25	20	25	0	0	0	27	28	28
Incoming Material	11	14	13	0	0	0	25	26	31
Total	**247**	**223**	**265**	**27**	**19**	**19**	**598**	**558**	**651**

361 HCT/P Deviation Reports by Manufacturing System FY14 – FY16

Table 6

Manufacturing System	Cellular HCT/Ps			Tissue HCT/Ps			Total		
	FY14	FY15	FY16	FY14	FY15	FY16	FY14	FY15	FY16
Processing & Processing Controls	76	71	75	14	5	13	90	76	88
Receipt, Pre-Distribution, Shipment & Distribution	57	48	37	22	21	22	79	69	59
Donor Eligibility	1	0	0	61	39	53	62	39	53
Donor Screening	4	0	7	31	35	13	35	35	20
Donor Testing	1	2	1	7	9	16	8	11	17
Recovery	1	7	7	2	3	3	3	10	10
Supplies and Reagents	4	6	5	3	1	3	7	7	8
Storage	2	0	2	5	4	1	7	4	3
Equipment	0	0	0	1	0	1	1	0	1
Labeling Controls	0	0	0	8	5	0	8	5	0
Environmental Control	0	0	0	1	0	0	1	0	0
Total	**146**	**134**	**134**	**155**	**122**	**125**	**301**	**256**	**259**

II. BPD Reports Submitted by Blood and Plasma Establishments:

General Overview

Blood and Source Plasma establishments submitted 4,546 more reports in FY16 than in the previous fiscal year (FY15-45,773) (Table 2). 98% of the total reports submitted in FY16 were submitted by blood and plasma establishments.

- Licensed blood establishments submitted four more reports in FY16 (FY15-18,660) (Table 4). 37% of the blood and plasma reports were submitted by licensed blood establishments.
    - There were 496 fewer reports involving post donation information (FY15-13,474, FY16-12,978).
        - 70% of the reports submitted in FY16 involved post donation information (FY15-72%).
    - There were 232 more reports involving donor screening (FY15-1,158, FY16-1,390).
        - 7% of the reports submitted in FY16 involved donor screening (FY15-6%)
    - There were 227 more reports involving miscellaneous deviations or unexpected events (FY15-1,143, FY16-1,370).
        - 7% of the reports submitted in FY16 involved miscellaneous deviations or unexpected events (FY15-6%).
    - There were 93 more reports involving quality control and distribution (FY15-1,122 FY16-1,215).
        - 7% of the reports submitted in FY16 involved quality control and distribution (FY15-6%).
    - There were nine more reports involving blood collection (FY15-868, FY16-877).
        - 5% of the reports submitted in FY16 involved blood collection (FY15-5%).
    - The following events represented approximately 5% (total FY15-5%, FY16-4%) of the reports submitted by licensed blood establishments:
        - There were 47 fewer reports involving labeling (FY15-482, FY16-435).
        - There were 39 fewer reports involving routine testing (FY15-232, FY16-193).
        - There were 19 more reports involving component preparation (FY15-150, FY16-169).
        - The number of reports involving donor deferral was similar to the number of reports submitted the previous year (25 in FY15 compared to 24 in FY16).
        - There were seven more reports involving viral testing (FY15-6, FY16-13).

- Unlicensed registered blood establishments submitted 482 more reports in FY16 (FY15-3,093) (Table 4). 7% of the blood and plasma reports were submitted by unlicensed registered blood establishments.
    - There were 345 more reports involving quality control and distribution (FY15-1,660 FY16-2,005).

        - 56% of the reports submitted in FY16 involved quality control and distribution (FY15-54%).
    - There were 80 more reports involving labeling (FY15-727, FY16-807).
        - 23% of the reports submitted in FY16 involved labeling (FY15-24%).
    - There were 13 more reports involving post donation information (FY15-313, FY16-326).
        - 9% of the reports submitted in FY16 involved post donation information (FY15-10%).
    - There were 34 more reports involving routine testing (FY15-236, FY16-270).
        - 8% of the reports submitted in FY16 involved routine testing (FY15-8%).
    - The following events represented approximately 5% (total FY15-4%, FY16-5%) of the report submitted by unlicensed registered blood establishments:
        - There were 17 more reports involving component preparation (FY15-52, FY16-69).
        - There were 30 more reports involving donor screening (FY15-25, FY16-55).
        - There were 35 fewer reports involving blood collection (FY15-56, FY16-21).
        - The number of reports involving miscellaneous deviations or unexpected events was similar to the number of reports submitted the previous year (17 in FY15 compared to 14 in FY16).
        - The number of reports involving donor deferral was similar to the number of reports submitted the previous year (five in FY15 compared to seven in FY16).
        - The number of reports involving viral testing was similar to the number of reports submitted the previous year (two in FY15 compared to one in FY16).

- Transfusion services submitted 130 more reports in FY16 (FY15-1,826) (Table 4). 4% of the blood and plasma reports were submitted by transfusion service.
    - Transfusion services typically report few BPDs and may file no reports in a given year. For example, 425 (66%) of those reporting in FY16 submitted one or two reports and only 116 (18%) transfusion services submitted more than five reports during FY16.
    - There were 74 more reports involving quality control and distribution (FY-15-1,073, FY16-1,147).
        - 59% of the reports submitted in FY16 involved quality control and distribution (FY15-59%)
    - There were 16 more reports involving labeling (FY15-424, FY16-440).
        - 22% of the reports submitted in FY16 involved labeling (FY15-23%)
    - There were 38 more reports involving routine testing (FY15-326, FY16-364).
        - 19% of the reports submitted in FY16 involved routine testing (FY15-18%)

  - The number of reports involving component preparation was similar to the number of reports submitted the previous year (three in FY15 compared to five in FY16).

- Source Plasma establishments submitted 3,930 more reports in FY16 (FY15-22,194) (Table 4). 52% of the blood and Source Plasma reports were submitted by Source Plasma establishments. One Source Plasma center submitted 2,970 more reports in FY16. 248 reports submitted by that Source Plasma center were submitted by 18 locations licensed after FY15.
  - There were 3,372 more reports involving post donation information (FY15-18,942, FY16-22,314).
    - 85% of the reports submitted in FY16 involved post donation information (FY15-85%).
  - There were 275 more reports involving miscellaneous deviations or unexpected events (FY15-2,520, FY16-2,795).
    - 11% of the reports submitted in FY16 involved miscellaneous deviations or unexpected events (FY15-11%).
  - There were 206 more reports involving quality control and distribution (FY15-567, FY16-773).
    - 3% of the reports submitted in FY16 involved quality control and distribution (FY15-3%).
  - The following events represented less than 5% (total FY15-1%, FY16-1%) of the report submitted by Source Plasma establishments:
    - There were 38 more reports involving donor screening (FY15-145, FY16-183).
    - There were 30 more reports involving labeling (FY15-five, FY16-35).
    - There were seven more reports involving donor deferral (FY15-11, FY16-18).
    - The number of reports involving collection was similar to the number of reports submitted the previous year (four in FY15 compared to five in FY16).
    - There were no reports involving component preparation submitted in FY15 and one report submitted in FY16.

Total BPDRs by Manufacturing System
Blood and Source Plasma Establishments
FY16

Table 7

Manufacturing System	Licensed Blood Establishments	Unlicensed Blood Establishments	Transfusion Services	Source Plasma Establishments	Total	
DE-Post Donation Information	12,978	326	NA	22,314	35,618	70.8%
QC & Distribution	1,215	2,005	1,147	773	5,140	10.2%
Miscellaneous	1,370	14	NA	2,795	4,179	8.3%
Labeling	435	807	440	35	1,717	3.4%
DE-Donor Screening	1,390	55	NA	183	1,628	3.2%
Blood Collection	877	21	NA	5	903	1.8%
LT-Routine Testing	193	270	364	0	827	1.6%
Component Preparation	169	69	5	1	244	0.5%
DE-Donor Deferral	24	7	NA	18	49	0.1%
LT-Viral Testing	13	1	NA	0	14	<0.1%
Total	**18,664**	**3,575**	**1,956**	**26,124**	**50,319**	100%

DE-Donor Eligibility
LT-Laboratory Testing
NA-Not applicable: manufacturing not performed in transfusion service

Post Donation Information

Post donation information (PDI) continues to be the most frequently reported event associated with the manufacturing of blood and plasma products (71% of deviation reports) (Tables 3 and 7). The number of reports blood and plasma establishments submitted involving post donation information increased 9% from the previous fiscal year (FY15-32,729, FY16-35,618) (Table 4).

- Blood establishments submitted 483 fewer reports involving post donation information, which is a decrease of 4%, in FY16 compared to FY15 (Table 8).
    - They submitted 39 fewer reports involving a donor who traveled to a malarial risk area, 291 fewer reports involving a donor who traveled to a vCJD risk area, 128 fewer reports involving a donor who received a tattoo and/or piercing, and 119 more reports involving a donor with a history of taking finasteride, Tegison, Accutane, or Avodart, Jalyn, or Absorica, and 20 more reports involving a male donor who had a history of sex with another male.
- Source Plasma establishments submitted 3,372 more reports involving post donation information, which is an increase of 18% in FY16 compared to FY15 (Table 8).
    - They submitted 1,140 more reports involving a donor who had a history of tattoo and/or piercing, 565 more reports involving a donor who tested positive for a viral maker at another center, 656 more reports involving a donor who had a positive drug screen, and 344 more reports involving a donor who had a history of incarceration.

Table 8 illustrates the major differences in post donation information reports from FY14 to FY16. Only the five most frequently reported categories are included in the table.

PDI Reports Submitted by Blood and Source Plasma Establishments

Table 8

Blood Establishments	**FY14**	**FY15**	**FY16**
Post Donation Information (PD) – *total*	16,065	13,787	13,304
Donor had a history of travel to malarial risk area (PD1236)	5,460	4,223	4,184
Donor had a history of travel to vCJD risk area (PD1242)	2,684	2,393	2,102
Donor had history of male to male sex (PD1214)	1,041	922	942
Donor received finasteride, Tegison, Accutane, or Avodart, Jalyn, or Absorica (PD1245)	829	761	880
Donor received tattoo and/or piercing (PD1259)	1,253	973	845

Source Plasma Establishments	**FY14**	**FY15**	**FY16**
Post Donation Information (PD) – *total*	20,007	18,942	22,314
Donor received tattoo and/or piercing (PD1259)	13,303	12,975	14,115
Donor tested reactive at another center, specific testing unknown (PD1114)	1,119	1,116	1,681
Positive drug screen (PD1254)	865	925	1,581
Donor had a history of incarceration (PD1249)	826	844	1,187
Intimate contact with risk for a relevant transfusion-transmitted infection - HCV (PD1264)	1,039	666	668

Note: All post donation information reports are not included in this table.

Miscellaneous

The total number of miscellaneous reports increased 14% from the previous fiscal year (FY15-3,680, FY16-4,179) (Table 4). The majority of these reports involved the distribution of a unit that was collected from a donor who subsequently tested confirmed positive for a viral marker on a later donation (FY15-3,652, FY16-4,155).

- The number of these reports submitted by blood establishments increased 20% (FY15-1,132, FY16-1,360) from the previous fiscal year (Table 9).
- The number of these reports submitted by Source Plasma establishments increased 11% (FY15-2,520, FY16-2,795) from the previous fiscal year (Table 9).

Table 9 illustrates the number of reports from FY12 to FY16 related to units collected from donors who subsequently tested confirmed positive for selected viral markers (lookback). *Note: All lookback reports are not included in these tables.*

Viral Marker Lookback Reports
Submitted by Blood and Source Plasma Establishments

Table 9

Blood Establishments	**FY12**	**FY13**	**FY14**	**FY15**	**FY16**
Lookback; Subsequent unit confirmed positive (MI02) - *total*	927	1,140	1,202	1,132	1,360
HBV (MI0203)	140	343	412	568	435
HCV (MI0204)	506	470	421	321	319
HIV (MI0202)	180	200	191	129	127

Source Plasma Establishments	**FY12**	**FY13**	**FY14**	**FY15**	**FY16**
Lookback; Subsequent unit confirmed positive (MI02) - *total*	1,988	2,093	2,523	2,520	2,795
HCV (MI0204)	1,270	1,435	1,643	1,677	1,806
HBV (MI0203)	472	390	578	508	593
HIV (MI0202)	243	264	296	316	391

A. Most Frequent BPD Reports Submitted by Licensed Blood Establishments[4]

Of the 18,664 reports (Table 7) submitted by licensed blood establishments, 12,978 (69.5%) reports involved **post donation information** (Table 10).

- The number of these reports decreased 4% (FY15-13,474).
- The number of reports in which a donor or third party provided subsequent information related to high risk behavior or history decreased 4% (FY15-12,445).
    - The number of reports in which a donor or third party provided subsequent information regarding receiving finasteride, Tegison, Accutane, Avodart, Jalyn, or Absorica increased 15% (FY15-746).
    - The number of reports in which a donor or third party provided subsequent information regarding male to male sex increased 2% (FY15-905).
    - The number of reports in which a donor or third party provided subsequent information regarding received a tattoo and/or piercing decreased 13% (FY15-951).
    - The number of reports in which a donor or third party provided subsequent information regarding travel to a vCJD risk area decreased 12% (FY15-2,311).
    - The number of reports in which a donor or third party provided subsequent information regarding travel to a malaria risk area decreased 1% (FY15-4,137).
- The number of reports in which a donor or third party provided subsequent information related to a post donation illness increased 5% (FY15-885).
    - The number of reports in which a donor had a fever or diarrhea post donation was similar to the number of reports submitted the previous year (463 in FY15 compared to 459 in FY16).
- The number of reports in which a donor or third party provided subsequent information related to the donor testing positive decreased from 115 in FY15 to 102 in FY16.

[4] Licensed blood establishments do not include Source Plasma establishments, for the purpose of this summary.

Most Frequent BPD Reports - Post Donation Information
From *Licensed Blood Establishments*

Table 10

POST DONATION INFORMATION (PD) 12,978	# Reports	% of Total (PD)
Behavior/History	***11,908***	***91.8%***
Travel to malaria endemic area/history of malaria	4,079	31.4%
Risk factors associated with Creutzfeldt-Jakob Disease (CJD) – travel	2,030	15.6%
Male donor had sex with another man	923	7.1%
Received finasteride, Tegison, Accutane, Avodart, Jalyn, or Absorica	858	6.6%
Donor received tattoo and/or piercing	829	6.4%
Illness	***932***	***7.2%***
Post donation illness (not hepatitis, HIV, HTLV-I, STD, cancer or cold/flu related)	837	6.4%
Fever/diarrhea	459	3.5%
Infection	242	1.9%
Post donation diagnosis or symptoms of HIV, or reactive test for HIV	32	0.2%
Post donation diagnosis or symptoms of HCV, or reactive test for HCV	25	0.2%
Post donation diagnosis or symptoms of non-specific hepatitis, reactive test for non-specific hepatitis, or elevated liver enzymes	12	0.1%
Testing *	***102***	***0.8%***
Tested reactive for HIV prior to donation	45	0.3%
Tested reactive for Hepatitis B prior to donation	18	0.1%
Tested reactive for Hepatitis C prior to donation	17	0.1%
Tested reactive for HTLV prior to donation	8	0.1%
Not specifically related to high risk behavior	***36***	***0.3%***
Donated to be tested or called back for test results	19	0.1%
Donor does not want their blood used	16	0.1%

*Includes testing positive for viral marker prior to donation at another location

Note: All post donation information reports are not included in this table.

Of the 18,664 reports (Table 7) submitted by licensed blood establishments, 1,390 (7.4%) reports involved **donor screening** deviations or unexpected events (Table 11).

- The number of these reports increased 20% (FY15-1,158).
- The number of reports in which the deferral screening was not done or incorrectly performed, including using the incorrect donor identification, to determine if the donor was previously deferred increased 34% (FY15-675).
    - 90% of these reports involve donors who were not previously deferred
- The number of reports in which the donor record was incomplete or incorrect increased 10% (FY15-253).
    - 92% of these reports involve donor history question that were incomplete or not documented. Most of these related to asking the incorrect gender specific questions.
- The number of reports in which the donor gave a history that warranted deferral or follow up and was not deferred or follow up questions were not asked, decreased from 208 in FY15 to 187 in FY16.

Most Frequent BPD Reports – Donor Screening
From *Licensed Blood Establishments*

Table 11

DONOR SCREENING (DS) 1,390	# Reports	% of Total (DS)
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***906***	***65.2%***
Donor not previously deferred	818	58.8%
Donor previously deferred due to history	50	3.6%
Donor previously deferred due to testing	38	2.7%
Donor record incomplete or incorrect	***278***	***20.0%***
Donor history questions	256	18.4%
Incorrect gender specific question asked or incorrect answer	150	10.8%
Donor identification	12	0.9%
Donor signature missing	6	0.4%
Donor confidentiality compromised	2	0.1%
Donor gave history which warranted deferral or follow up and was not deferred	***187***	***13.5%***
Travel to malaria endemic area/history of malaria	96	6.9%
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel	41	2.9%
Donor did not meet acceptance criteria	***19***	***1.4%***
Hemoglobin or Hematocrit unacceptable or not documented or testing was performed incorrectly	7	0.5%
Medical review or physical not performed or inadequate	7	0.5%

Note: All donor screening reports are not included in this table.

Of the 18,664 reports (Table 7) submitted by licensed blood establishments, 1,370 (7.3%) reports involved **miscellaneous** deviations or unexpected events (Table 12)**.**

- The number of these reports increased 20% (FY15-1,143).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for a viral marker increased 21% (FY15-1,117).
    - The number of reports in which a donor subsequently tested confirmed positive for HCV was similar to the number of reports submitted the previous year (321 in FY15 compared to 316 in FY16).
    - The number of reports in which a donor subsequently tested confirmed positive for HIV was similar to the number of reports submitted the previous year (127 in FY15 compared to 124 in FY16).
    - The number of reports in which a donor subsequently tested confirmed positive for HBV decreased from 566 in FY15 to 431 in FY16.
        - The number of reports in which a donor tested repeat reactive on two occasions for anti-HBc, decreased from 504 in FY15 to 369 in FY16.
    - The number of reports in which a donor subsequently tested positive (using an IND test) for Babesia increased from five in FY15 to 384 in FY16.
- The number of reports in which a donor was either implicated in or not ruled out of a transfusion associated disease was similar to the number of reports submitted the previous year (26 in FY15 compared to 23 in FY16).
    - There were 18 reports submitted in FY16 (20 in FY15) involving Babesia.
    - There were four reports submitted in FY16 (three in FY15) involving Hepatitis.
        - There were two reports involving Hepatitis C submitted in FY16 (FY15-one). In one case, a donor was identified as positive for HCV.
        - There were two reports involving Hepatitis B submitted in FY16 (FY15-two).

Most Frequent BPD Reports - Miscellaneous
From *Licensed Blood Establishments*

Table 12

MISCELLANEOUS (MI) 1,370	# Reports	% of Total (MI)
Lookback; subsequent unit tested confirmed positive for:	***1,347***	***98.3%***
HBV	431	31.5%
Anti-HBc positive	369	26.9%
Babesia	384	28.0%
HCV	316	23.1%
HIV	124	9.1%
West Nile Virus	70	5.1%
HTLV	9	0.7%
Chagas	8	0.6%
Donor implicated in transfusion associated disease	***23***	***1.7%***
Babesia	18	1.3%
Hepatitis B	2	0.1%
Hepatitis C	2	0.1%

Note: All miscellaneous reports are not included in this table.

Of the 18,664 reports (Table 7) submitted by licensed blood establishments, 1,215 (6.5%) reports involved **quality control and distribution** deviations or unexpected events (Table 13).

- The number of these reports increased 8% (FY15-1,122).
- The number of reports involving the distribution of a product that did not meet specifications increased from 623 in FY15 to 790 in FY16.
    - The number of reports involving the release of a product in which product QC was unacceptable, not performed, not documented, or incomplete increased from 405 in FY15 to 557 in FY16. The number of reports related to bacterial detection testing increased from 238 in FY15 to 305 in FY16.
- The number of reports involving shipping and storage decreased from 268 in FY15 to 170 in FY16.
- The number of reports involving distribution procedures not performed in accordance with blood bank transfusion service's specification increased from 128 in FY15 to 143 in FY16.

Most Frequent BPD Reports –Quality Control & Distribution
From *Licensed Blood Establishments*

Table 13

QC & DISTRIBUTION (QC) 1,215	# Reports	% of Total (QC)
Distribution of product that did not meet specifications	***790***	***65.0%***
Product QC unacceptable, not performed, not documented, or incomplete	557	45.9%
Bacterial detection testing	305	25.1%
White Blood Cell count	102	8.4%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or documented	53	4.4%
Product identified as unsuitable due to a donor screening deviation or unexpected event	33	2.7%
Product identified as unsuitable due to a collection deviation or unexpected event	32	2.6%
Product identified as unsuitable due to a component preparation deviation or unexpected event	29	2.4%
Product in which specification other than QC was not met	25	2.1%
Shipping and storage	***170***	***14.0%***
Product not packaged in accordance with specifications or no documentation that product was packed appropriately	48	4.0%
No documentation that product was shipped or stored at appropriate temperature	39	3.2%
Product arrived at consignee at unacceptable temperature	26	2.1%
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***143***	***11.8%***
Improper product selected for patient	29	2.4%
Product not documented or incorrectly documented as issued in the computer	26	2.1%
Product not irradiated as required	20	1.6%
Improper ABO or Rh type selected for patient	20	1.6%
Testing not performed, incompletely performed, or not documented	***64***	***5.3%***
Antigen screen	19	1.6%
ABO and/or Rh	12	1.0%

Note: All post donation information reports are not included in this table.

Of the 18,664 (Table 7) reports submitted by licensed blood establishments, 877 (4.7%) reports involved **blood collection** deviations or unexpected events (Table 14)**.**

- The number of these reports increased 1% (FY15-868).
- The number of reports involving the collection process decreased from 779 in FY15 to 760 in FY16.
    - The number of reports involving clotted units was similar to the number of reports submitted the previous year (721 in FY15 compared to 726 in FY16).
    - The number of reports in which the sterility of a product may have been compromised increased from 67 in FY15 to 107 in FY16.
        - The number of reports involving bacterial contamination, discovered as a result of a patient transfusion reaction, increased from 49 in FY15 to 80 in FY16. The most common organisms identified were Staphylococcus coagulase negative and Staphylococcus epidermidis.

Most Frequent BPD Reports – Blood Collection
From *Licensed Blood Establishments*

Table 14

BLOOD COLLECTION (BC) 877	#Reports	% of Total (BC)
Collection process	***760***	***86.7%***
Product contained clots or fibrin, not discovered prior to distribution	726	82.8%
Product hemolyzed, not discovered prior to distribution	16	1.8%
Donor sample tube mix-up or donor sample tube mislabeled	9	1.0%
Apheresis collection process	1	0.1%
Sterility compromised	***107***	***12.2%***
Bacterial contamination	80	9.1%
Arm prep not performed or performed inappropriately	15	1.7%
Air contamination	11	1.3%
Collection bag	***7***	***0.8%***
Blood drawn into outdated bag	2	0.2%

Note: All blood collection reports are not included in this table.

B. Most Frequent BPD Reports Submitted by Unlicensed Registered Blood Establishments

Of the 3,575 reports (Table 7) submitted by unlicensed registered blood establishments, 2,005 (56.1%) involved **quality control and distribution** deviations or unexpected events (Table 15)**.**

- The number of these reports increased 21% (FY15-1,660).
- The number of reports involving distribution procedures not performed in accordance with the blood bank transfusion service's specifications increased 26% (FY15-1,311).
    - The number of reports involving the release of a product that was not documented or incorrectly documented as issued in the computer, which was the only method of documenting the visual and clerical checks at the time of distribution, increased 18% (FY15-681).
    - The number of reports involving the product not irradiated as required increased from 157 in FY15 to 196 in FY16.
- The number of reports involving testing that was not performed, incompletely performed, or not documented decreased from 180 in FY15 to 169 in FY16.

Most Frequent BPD Reports - Quality Control & Distribution
From *Unlicensed Registered Blood Establishments*

Table 15

QC & DISTRIBUTION (QC) 2,005	# Reports	% of Total (QC)
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***1,655***	***82.5%***
Product not documented or incorrectly documented as issued in the computer	803	40.0%
Product not irradiated as required	196	9.8%
Improper product selected for patient	195	9.7%
Improper ABO or Rh type selected for patient	104	5.2%
Procedure for issuing not performed or documented in accordance with specifications	94	4.7%
Product issued to wrong patient	60	3.0%
Testing not performed, incompletely performed, or not documented	***169***	***8.4%***
Antibody screen or identification	39	1.9%
Antigen screen	38	1.9%
ABO and/or Rh	37	1.8%
Compatibility	25	1.2%
Distribution of product that did not meet specifications	***124***	***6.2%***
Product QC unacceptable, not performed, not documented or incomplete	39	1.9%
Bacterial detection testing	18	0.9%
Outdated product	30	1.5%
Product in which instrument QC, calibration, or validation unacceptable, incomplete or not documented	28	1.4%
Product in which specification other than QC not met	8	0.4%
Shipping and storage	***51***	***2.5%***
Temperature not recorded or unacceptable upon return, unit redistributed	18	0.9%
No documentation that product was shipped or stored at appropriate temperature	18	0.9%

Note: All QC & distribution reports are not included in this table.

Of the 3,575 reports (Table 7) submitted by unlicensed registered blood establishments, 807 (22.6%) involved **labeling** deviations or unexpected events (Table 16).

- The number of these reports increased 11% (FY15-727).
- The number of reports involving the crossmatch tag, tie tag, or transfusion record labeled with incorrect or missing information increased 7% (FY15-516).
    - The number of reports involving the crossmatch tags or transfused records switched, but both units were intended for the same patient increased from 144 in FY15 to 163 in FY16.
- The number of reports involving the unit labeled with incorrect or missing information increased from 211 in FY15 to 257 in FY16.
    - The number of reports involving the expiration date extended or missing on the product label increased from 86 in FY15 to 110 in FY16.
    - The number of reports involving the product type or code incorrect or missing on the product label increased from 25 in FY15 to 41 in FY16.

Most Frequent BPD Reports - Labeling
From *Unlicensed Registered Blood Establishments*

Table 16

LABELING (LA) 807	#Reports	% of Total (LA)
Crossmatch tag, tie tag, to transfusion record incorrect or missing information	***550***	***68.2%***
Crossmatch tags or transfused records switched, both units intended for the same patient	163	20.2%
Recipient identification incorrect or missing	133	16.5%
Crossmatch tag, tie tag, or transfusion record incorrect or missing or attached to incorrect unit	48	5.9%
Unit, lot, or pool number incorrect or missing	39	4.8%
Expiration date or time extended or missing	38	4.7%
Product type or code incorrect or missing	37	4.6%
Labels applied to blood unit or product incorrect or missing information	***257***	***31.8%***
Extended or missing expiration date or time	110	13.6%
Product type or code incorrect or missing	41	5.1%
Irradiation status incorrect or missing	34	4.2%
HLA type incorrect or missing	20	2.5%
Combination of incorrect or missing information	15	1.9%
Donor/unit number or lot number incorrect or missing	12	1.5%

Note: All labeling reports are not included in this table.

Of the 3,575 reports (Table 7) submitted by unlicensed registered blood establishments, 326 (9.1%) reports involved **post donation information** (Table 17)**.**

- The number of these reports increased 4% (FY15-313).
- The number of reports in which a donor or third party provided subsequent information related to high risk behavior or history increased from 300 in FY15 to 312 in FY16.
    - The number of reports in which a donor or third party provided subsequent information regarding travel to a malarial risk area increased from 86 in FY15 to 105 in FY16.
    - The number of reports in which a donor or third party provided subsequent information regarding travel to a vCJD risk area decreased from 82 in FY15 to 72 in FY16.
- The number of reports in which a donor or third party provided subsequent information related to post donation illness was similar to the number of reports submitted the previous year (eight in FY15 compared to 11 in FY16).

Most Frequent BPD Reports - Post Donation Information
From *Unlicensed Registered Blood Establishments*

Table 17

POST DONATION INFORMATION (PD) 326	# Reports	% of Total (PD)
Behavior/History	***312***	***95.7%***
Travel to malaria endemic area/history of malaria	105	32.2%
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) – travel	72	22.1%
Received finasteride, Tegison, Accutane, Avodart, Jalyn, or Absorica	22	6.7%
Male donor had sex with another man	19	5.8%
Donor received tattoo and/or piercing	16	4.9%
Illness	***11***	***3.4%***

Note: All post donation information reports are not included in this table.

Of the 3,575 reports (Table 7) submitted by unlicensed registered blood establishments, 270 (7.6%) reports involved **routine testing** deviations or unexpected events (Table 18)**.**

- The number of these reports increased 14% (FY15-236).
- The number of reports involving testing performed, interpreted or documented incorrectly increased from 123 in FY15 to 159 in FY16.
- The number of reports involving sample identification decreased from 66 in FY15 to 49 in FY16.
- The number of reports involving unacceptable reagent QC or the use of expired reagents increased from 47 in FY15 to 62 in FY16.

Most Frequent BPD Reports - Routine Testing
From *Unlicensed Registered Blood Establishments*

Table 18

ROUTINE TESTING (RT) 270	# Reports	% of Total (RT)
Testing performed, interpreted, or documented incorrectly	***159***	***58.9%***
Compatibility	68	25.2%
Antibody screening or identification	47	17.4%
Antigen typing	21	7.8%
ABO and/or Rh	13	4.8%
Sample (used for testing) identification	***49***	***18.1%***
Sample used for testing was incorrectly or incompletely labeled	30	11.1%
Unsuitable sample used for testing (e.g., too old)	10	3.7%
Incorrect sample tested	9	3.3%
Reagent QC unacceptable or expired reagents used	***62***	***23.0%***
Antigen typing	18	6.7%
Antibody screening or identification	13	4.8%
Multiple testing	13	4.8%
ABO and/or Rh	11	4.1%

Note: All routine testing reports are not included in this table.

C. Most Frequent BPD Reports Submitted by Transfusion Services

Of the 1,956 reports (Table 7) submitted by transfusion services, 1,147 (58.6%) reports involved **quality control and distribution** deviations or unexpected events (Table 19).

- The number of these reports increased 7% (FY15-1,073).
- The number of reports involving distribution procedures not performed in accordance with the blood bank transfusion service's specifications increased 11% (FY15-745).
    - The number of reports involving the release of a product that was not documented or incorrectly documented as issued in the computer, which was the only method of documenting the visual and clerical checks at the time of distribution, increased 10% (FY15-332).
- The number of reports in which testing was not performed, incompletely performed, or not documented decreased 7% (FY15-228).
    - The number of reports in which ABO/Rh typing was not performed, incompletely performed, or not documented decreased from 72 in FY15 to 55 in FY16.
    - The number of reports in which antibody screening was not performed, incompletely performed, or not documented decreased from 56 in FY15 to 47 in FY16.

Most Frequent BPD Reports - Quality Control & Distribution
From *Transfusion Services*

Table 19

QC & DISTRIBUTION (QC) 1,147	# Reports	% of Total (QC)
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***829***	***72.3%***
Product not documented or incorrectly documented as issued in the computer	364	31.7%
Product not irradiated as required	110	9.6%
Procedure for issuing not performed or documented in accordance with specifications	101	8.8%
Improper product selected for patient	67	5.8%
Improper ABO or Rh type selected for patient	52	4.5%
Testing not performed, incompletely performed, or not documented	***212***	***18.5%***
ABO and/or Rh	55	4.8%
Antigen screen	51	4.4%
Antibody screen or identification	47	4.1%
Compatibility	31	2.7%
Distribution of product that did not meet specifications	***54***	***4.7%***
Outdated product	23	2.0%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or not documented	21	1.8%
Shipping and storage	***47***	***4.1%***
Temperature not recorded or unacceptable upon return, unit redistributed	19	1.7%
Stored at incorrect temperature	13	1.1%
No documentation that product was shipped or stored at appropriate temperature	12	1.0%

Note: All QC & distribution reports are not included in this table.

Of the 1,956 reports (Table 7) submitted by transfusion services, 440 (22.5%) reports involved **labeling** deviations or unexpected events (Table 20)**.**

- The number of these reports increased 4% (FY15-424).
- The number of reports involving the crossmatch, tie tag, or transfusion record labeled with incorrect or missing information increased from 359 in FY15 to 372 in FY16.
- The number of reports involving the unit labeled with incorrect or missing information was similar to the number of reports submitted the previous year (64 in FY15 compared to 67 in FY16).

Most Frequent BPD Reports - Labeling
From *Transfusion Services*

Table 20

LABELING (LA) 440	# Reports	% of Total (LA)
Crossmatch tag, tie tag or transfusion record incorrect or missing information	***372***	***84.5%***
Crossmatch tags or transfused records switched, both units intended for the same patient	110	25.0%
Recipient identification incorrect or missing	96	21.8%
Crossmatch tag or tie tag missing or attached to incorrect unit	34	7.7%
Product type or code incorrect or missing	25	5.7%
Unit, lot, or pool number incorrect or missing	23	5.2%
Expiration date or time extended or missing	18	4.1%
Labels applied to blood unit or product incorrect or missing information	***67***	***15.2%***
Extended or missing expiration date or time	34	7.7%
Product type/code and expiration date incorrect or missing	12	2.7%

Note: All labeling reports are not included in this table.

Of the 1,956 reports (Table 7) submitted by transfusion services, 364 (18.6%) reports involved **routine testing** deviations or unexpected events (Table 21).

- The number of these reports increased 12% (FY15-326).
- The number of reports involving testing performed, interpreted, or documented incorrectly increased from 199 in FY15 to 217 in FY16.
- The number of reports involving sample identification was similar to the number of reports submitted the previous year (58 in FY15 compared to 61 in FY16).
- The number of reports involving unacceptable reagent QC or the use of expired reagents increased from 69 in FY15 to 86 in FY16.

Most Frequent BPD Reports - Routine Testing
From *Transfusion Services*

Table 21

ROUTINE TESTING (RT) 364	# Reports	% of Total (RT)
Testing performed, interpreted, or documented incorrectly	***217***	***59.6%***
Compatibility	100	27.5%
Antibody screening or identification	53	14.6%
ABO and/or Rh typing	27	7.4%
Antigen typing	19	5.2%
Sample (used for testing) identification	***61***	***16.8%***
Sample used for testing was incorrectly or incompletely labeled	43	11.8%
Unsuitable sample used for testing	13	3.6%
Incorrect sample tested	5	1.4%
Reagent QC unacceptable or expired reagents used	***86***	***23.6%***
ABO and/or Rh typing	25	6.9%
Antibody screening or identification	24	6.6%
Multiple testing	18	4.9%
Antigen typing	14	3.8%

Note: All routine testing reports are not included in this table.

D. Most Frequent BPD Reports Submitted by Source Plasma Establishments

Of the 26,124 reports (Table 7) submitted by Source Plasma establishments, 22,314 (85.4%) involved **post donation information** (Table 22)**.**

- The number of these reports increased 18% (FY15-18,942).
- The number of reports in which a donor or third party provided subsequent information related to high risk behavior or history increased 16% (FY15-17,710).
    - The number of reports in which the donor had a history of a tattoo and/or piercing increased 9% (FY15-12,975).
    - The number of reports in which the donor subsequently tested positive on a drug screen increased 71% (FY15-925).
    - The number of reports in which the donor had a history of incarceration increased 41% (FY15-844).
    - The number of reports in which the donor had intimate contact with risk for hepatitis (Hepatitis C or Hepatitis B) increased 25% (FY15-859).
        - Hepatitis C: FY15-666; FY16-668
        - Hepatitis B: FY15-193; FY16-407
    - The number of reports in which a donor or third party provided subsequent information related to testing by another facility increased 51% (FY15-1,122). The majority of these reports involved a donor tested positive by another facility, but the specific testing was unknown (FY15-1,116).

Most Frequent BPD Reports - Post Donation Information
From *Source Plasma Establishments*

Table 22

POST DONATION INFORMATION (PD) 22,314	# Reports	% of Total (PD)
Behavior/History	***20,512***	***91.9%***
Donor received tattoo and/or piercing	14,115	63.3%
Positive drug screen	1,581	7.1%
Incarcerated	1,187	5.3%
Intimate contact with risk for a relevant transfusion-transmitted infection - HCV	668	3.0%
IV drug use	497	2.2%
Intimate contact with risk for a relevant transfusion-transmitted infection - HBV	407	1.8%
Testing*	***1,690***	***7.6%***
Tested reactive at another center, specific testing unknown	1,681	7.5%
Illness	***99***	***0.4%***
Post donation diagnosis or symptoms of HCV, or reactive test for HCV	36	0.2%
Post donation diagnosis or symptoms of HIV, or reactive test for HIV	29	0.1%
Post donation illness (not hepatitis, HIV, HTLV-I, STD, cancer, or cold/flu related)	23	0.1%

*Includes testing positive for viral marker prior to donation at another location

Note: All post donation information reports are not included in this table.

Of the 26,124 reports (Table 7) submitted by Source Plasma establishments, 2,795 (10.7%) reports involved **miscellaneous** deviations or unexpected events (Table 23).

- The number of these reports increased 11% (FY15-2,520).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for HCV increased 8% (FY15-1,677).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for HBV increased 17% (FY15- 508).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for HIV increased 24% (FY15-316).

Most Frequent BPD Reports - Miscellaneous
From *Source Plasma Establishments*

Table 23

MISCELLANEOUS (MI) 2,795	# Reports	% of Total (MI)
Lookback; subsequent unit tested confirmed positive for:	***2,795***	***100%***
HCV	1,806	64.6%
HBV	593	21.2%
HIV	391	14.0%
Multiple markers	5	0.2%

Note: All miscellaneous reports are not included in this table.

Of the 26,124 reports (Table 7) submitted by Source Plasma establishments, 773 (3.0%) involved **quality control and distribution** deviations or unexpected events (Table 24**).**

- The number of these reports increased 36% (FY15-567).
- The number of reports involving the distribution of a product with a positive test increased from 433 in FY15 to 684 in FY16. Most of these involved donors testing positive for atypical antibodies.
- The number of reports involving the distribution of a product in which testing was not performed, incompletely performed, or not documented decreased from 66 in FY15 to 14 in FY16.
- The number of reports involving the distribution of a product that should have been quarantined was similar to the number of reports submitted the previous year (68 in FY15 compared to 73 in FY16).
    - Fail to quarantine due to medical history (FY15-50, FY16-51),
    - Fail to quarantine due to donor screening deviation (FY15-6, FY16-9),
    - Fail to quarantine due to collection deviation (FY15-3, FY16-5),
    - Fail to quarantine due to viral testing deviation (FY15-6, FY16-5)

Most Frequent BPD Reports - Quality Control & Distribution
From *Source Plasma Establishments*

Table 24

QC & DISTRIBUTION (QC) 773	# Reports	% of Total (QC)
Positive testing for	***684***	***88.5%***
Antibody screen or identification	645	83.4%
Failure to quarantine unit due to medical history	***51***	***6.6%***
Donor received tattoo and/or piercing	11	1.4%
Positive drug screen	10	1.3%
Distribution of product that did not meet specifications	***22***	***2.8%***
Product identified as unsuitable due to a donor screening deviation or unexpected event	9	1.2%
Product identified as unsuitable due to a collection deviation or unexpected event	5	0.6%
Product identified as unsuitable due to a viral testing deviation or unexpected event	5	0.6%
Testing not performed, incompletely performed or not documented for	***14***	***1.8%***
Syphilis	9	1.2%
HIV/HCV/HBV Nucleic Acid Test (NAT)	3	0.4%

Note: All QC & distribution reports are not included in this table.

Of the 26,124 reports (Table 7) submitted by Source Plasma establishments, 183 (0.7%) reports involved **donor screening** deviations or unexpected events (Table 25).

- The number of these reports increased 26% (FY15-145)
- The number of reports involving incomplete or incorrect donor records increased from 55 in FY15 to 97 in FY16.
- The number of reports in which the donor gave a history that warranted deferral or follow up and was not deferred, or follow up questions were not asked, increased from 20 in FY15 to 39 in FY16.
- The number of reports involving donors who did not meet acceptance criteria decreased from 46 in FY15 to 24 in FY16.

Most Frequent BPD Reports - Donor Screening
From *Source Plasma Establishments*

Table 25

DONOR SCREENING (DS) 183	# Reports	% of Total (DS)
Donor record incomplete or incorrect	***97***	***53.0%***
Donor identification	45	24.6%
Donor history questions	44	24.0%
Donor gave history which warranted deferral or follow up and was not deferred	***39***	***21.3%***
Donor received tattoo and/or piercing	15	8.2%
Donor did not meet acceptance criteria	***24***	***13.1%***
Medical review or physical not performed or inadequate	15	8.2%
Unacceptable address or no proof of address	4	2.2%
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***23***	***12.6%***
Donor previously deferred due to history	12	6.6%
Donor previously deferred due to testing	4	2.2%
Donor not previously deferred	7	3.8%

Note: All donor screening reports are not included in this table.

III. BPD Reports Submitted by Licensed Manufacturers of Biological Products Other Than Blood and Blood Components (Licensed Non-Blood)

Licensed non-blood manufacturers submitted 93 more reports in FY16 than in the previous fiscal year (FY15-558) (Table 2). The number of reports submitted in FY16 by licensed non-blood manufacturers is displayed in Table 26.

- Allergenic manufacturers submitted seven more reports (FY15-82) (Table 5).
    - The number of reports involving product not meeting specifications was similar to the number of reports submitted the previous year (69 in FY15 compared to 71 in FY16). The majority (73%) related to precipitate discovered in allergenic extracts, which was similar to the number of reports submitted the previous year (61 in FY15 compared to 65 in FY16).
- Blood derivative manufacturers submitted 11 more reports (FY15-123) (Table 5).
    - The number of reports related to product specifications increased from 35 in FY15 to 57 in FY16.
        - The number of reports involving product specification not met for appearance was similar to the number of reports submitted the previous year (11 in FY15 compared to eight in FY16).
        - The number of reports involving the specification of a component packaged with a final product not met was similar to the number of reports submitted the previous year (17 in FY15 compared to 14 in FY16).
    - The number of reports related to process controls decreased from 27 in FY15 to 18 in FY16.
        - The number of reports related to process/procedures not performed or performed incorrectly was the same as the previous year (FY15-14).
        - The number of reports in which manufacturing or processing was performed using incorrect parameters decreased from 11 in FY15 to two in FY16.
- Licensed in-vitro diagnostic manufacturers submitted 33 more reports (FY15-111) (Table 5).
    - The number of reports related to the product specifications increased from 66 in FY15 to 97 in FY16.
        - The number of reports related to unexpected reactions in testing increased from 43 in FY15 to 61 in FY16.
        - The number of reports related to leaking vial or container due to loose or unsecure closures was similar to the number of reports submitted the previous year (11 in FY15 compared to 15 in FY16).
    - The number of reports related to quality control and distribution increased from 20 in FY15 to 29 in FY16. The number of reports related to the consignee receiving products upside down or sideways within the shipping container increased from seven in FY15 to 15 in FY16.

- Vaccine manufacturers submitted 42 more reports (FY15-223) (Table 5).
    - The number of reports involving product specifications increased from 74 in FY15 to 103 in FY16.
        - The number of reports involving product not meeting specifications increased from 47 in FY15 to 68 in FY16. Most of these were related to appearance (FY15-37, FY16-44).
        - The number of reports involving stability failures increased from 21 in FY15 to 28 in FY16. Most of these were related to potency (FY15-8, FY16-10).
    - The number of reports involving quality control and distribution increased from 30 in FY15 to 46 in FY16.
        - The number of reports involving broken or cracked vials increased from 23 in FY15 to 35 in FY16.
    - The number of reports involving process controls increased from 20 in FY15 to 40 in FY16.
        - The number of reports involving equipment cleaning procedures increased from 1 in FY15 to 12 in FY16.
    - The number of reports involving testing decreased from 43 in FY15 to 21 in FY16. Most of these were related to stability testing performed incorrectly or not performed (FY15-30, FY16-13).
- Licensed HCT/P manufacturers (351 HCT/Ps) submitted the same number of reports as the previous year (FY15-19) (Table 5).
    - The number of reports related to the labeling controls increased from eight in FY15 to 14 in FY16. Most of these involved the product labeled with the incorrect recipient identification (FY15-5, FY16-12).
    - The number of reports involving product specifications decreased from eight in FY15 to two in FY16.
    - There were two report submitted by HPC, Cord Blood manufacturers, which involved a labeling deviation and a testing deviation.

Total BPD Reports by Manufacturing System
Licensed Non-Blood Establishments
FY16

Table 26

Manufacturing System	Allergenic	Blood Derivative	In Vitro Diagnostic	Vaccine	351 HCT/P	TOTAL	
Product Specifications	71	57	97	103	2	330	50.7%
Quality Control & Distribution	1	18	29	46	0	94	14.4%
Process Controls	2	18	4	40	0	64	9.8%
Labeling	11	11	4	17	14	57	8.8%
Testing	4	13	6	21	3	47	7.2%
Incoming Material	0	15	3	13	0	31	4.8%
Miscellaneous	0	2	1	25	0	28	4.3%
Total	**89**	**134**	**144**	**265**	**19**	**651**	100%

IV. HCT/P Deviation Reports Submitted by Manufacturers of 361 HCT/Ps

The deviation reporting requirement for HCT/Ps regulated solely under section 361 of the PHS Act and 21 CFR Part 1271 became effective on May 25, 2005. HCT/Ps means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue[5] [21 CFR 1271.3(d)]. An HCT/P is regulated solely under Section 361 of the PHS Act and the regulations under 21 CFR Part 1271 if it meets all of the following criteria under 21 CFR 1271.10(a):

(1) The HCT/P is minimally manipulated;
(2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
(3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; **AND**
(4) Either:
    i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; **OR**
    ii) The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function**, AND**:
        (a) Is for autologous use;
        (b) Is for allogeneic use in a first or second-degree relative**; OR**
        (c) Is for reproductive use.

The following is a summary of HCT/P deviation reports submitted by manufacturers of 361 HCT/Ps during FY16. The summary does not provide individual product type specifics, but only by cellular (e.g., hematopoietic stem/progenitor cells) or tissue (e.g., skin, musculoskeletal, cornea) products.

[5] HCT/P Deviation reporting applies to nonreproductive HCT/Ps.

Manufacturers of 361 HCT/Ps submitted three more reports in FY16 than in the previous fiscal year (FY15-256) (Table 2). The number of reports submitted in FY16 by manufacturers of 361 HCT/Ps is displayed in Table 27.

- The same number of reports involving cellular HCT/Ps was submitted this fiscal year as compared to the previous fiscal year (FY15-134) (Table 6).
    - The number of reports involving processing and process controls was similar to the number of reports submitted the previous year (71 in FY15 compared to 75 in FY16). The number of reports involving contamination or potential contamination during processing was similar to the number of reports submitted the previous year (71 in FY15 compared to 73 in FY16).
    - The number of reports involving receipt, pre-distribution, shipment and distribution decreased from 48 in FY15 to 37 in FY16. The number of reports involving distribution of product that was contaminated or potentially contaminated decreased from 44 in FY15 to 31 in FY16.
- There were three more reports involving tissue HCT/Ps submitted than in the previous fiscal year (FY15-122, FY16-125) (Table 6).
    - The number of reports involving donor eligibility increased from 33 in FY15 to 53 in FY16.
        - There were 19 fewer reports involving the acceptance of ineligible donors (FY15-33, FY16-52). In FY16, 47 of these reports involved risk factors, clinical or physical evidence identified.
    - The number of reports involving donor screening decreased from 35 in FY15 to 13 in FY16.
        - The number of reports in which the donor medical history interview was not performed or performed incorrectly decreased from 27 in FY15 to seven in FY16.
    - The number of reports involving donor testing was similar to the number of reports submitted the previous year (15 in FY15 compared to 16 in FY16).
        - The number of reports involving unacceptable samples used for testing was the same as the number of reports submitted the previous year (FY15-11).
            - Four of these reports involved samples that did not meet requirements in test kit package insert.
            - Nine of these reports involved samples collected from donors who were incorrectly evaluated or not evaluated for plasma dilution.
        - The number of reports in which testing was not performed or performed incorrectly were similar to the number of reports submitted the previous year (four in FY15 compared to three in FY16). There were two reports involving testing for syphilis and one report involving testing for HBV.
    - The number of reports involving receipt, pre-distribution, shipment and distribution was similar to the number of reports submitted the previous year (21 in FY15 compared to 22 in FY16).
        - The number of reports involving inappropriate shipping conditions related to packaging decreased from 16 in FY15 to 10 in FY16.

- The number of reports involving processing and processing controls increased from five in FY15 to 13 in FY16.

Total Reports by Manufacturing System
361 HCT/P Establishments
FY16

Table 27

HCT/P Deviation Code	Cellular HCT/P	Tissue HCT/P	Total	
Processing and Processing Controls	75	13	88	34.0%
Receipt, Pre-Distribution, Shipment & Distribution	37	22	59	22.8%
Donor Eligibility	0	53	53	20.5%
Donor Screening	7	13	20	7.7%
Donor Testing	1	16	17	6.6%
Recovery	7	3	10	3.9%
Supplies and Reagents	5	3	8	3.1%
Storage	2	1	3	1.2%
Equipment	0	1	1	0.4%
Labeling Controls	0	0	0	0.0%
Environmental Control	0	0	0	0.0%
Total	**134**	**125**	**259**	**100%**

V. Attachments

1 – Table-Number of BPD Reports by Type of Blood and Source Plasma Establishment
2 – List of BPD Codes for Blood and Source Plasma Establishments
3 – Table-Number of BPD Reports by Type of Licensed Non-Blood Establishment
4 – List of BPD Codes for Licensed Non-Blood Establishments
5 – Table-Number of HCT/P Deviation Reports by Type of 361 HCT/P Establishment
6 – List of HCT/P Deviation Codes for 361 HCT/P Establishments
7 – List of Tables in Annual Summary Report

VI. References

1. Guidance for Industry - Biological Product Deviation Reporting for Blood and Plasma Establishments 10/18/2006
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm073455.htm

2. Guidance for Industry - Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components 10/18/2006
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/ucm163893.htm

3. Draft Guidance for Industry - Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271 12/2015
http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM478826.pdf