Biological Product and HCT/P Deviation Reports –

Annual Summary for Fiscal Year 2017

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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 manufacturers are required to submit Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) 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 HCT/Ps 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 Source 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 guidance document for deviation reporting for 361 HCT/Ps (Ref. 3) was published in September 2017, and may be found at https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM574889.pdf

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 and HCT/P deviation codes. These data may or may not be included in accompanying tables. Detailed counts for all BPD and HCT/P deviation 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 reviewing the estimated collections and transfusions made in the United States across several years. In calendar year 2011, an estimated 17.7 million whole blood and red blood cells products were collected with 21 million transfusions.[1] In calendar year 2013, an estimated 14.2 million whole blood and red blood cells products were collected with 19 million transfusions.[2] In calendar year 2015, an estimated 12.6 million whole blood and red blood cells products were collected with 11.3 million transfusions.[3] In addition, there were 32.6 million Source Plasma donations in 2014, 35.5 million Source Plasma donations in 2015, and 38.3 million Source Plasma donations in 2016.[4]

During fiscal year 2017 (hereafter FY17), encompassing October 1, 2016, through September 30, 2017, CBER's Office of Compliance and Biologics Quality/Division of Inspections and Surveillance entered 52,231 deviation reports into the BPD and HCT/P deviation database (Table 1):

- We received more than 52,231 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 1.9% increase in the number of reports we received in FY17 (1,002 reports) compared to FY16 (Table 2).
    - Blood and Source Plasma establishments submitted 1,115 more reports in FY17 compared to FY16 (Table 2).
        - Licensed blood establishments submitted 708 fewer reports in FY17.
        - Unlicensed registered blood establishments submitted 277 fewer reports in FY17.
        - Transfusion services submitted 124 more reports in FY17.
        - Source Plasma establishments submitted 1,976 more reports in FY17.
    - Manufacturers of licensed biological products other than blood and blood components submitted 75 fewer reports in FY17 compared to FY16 (Table 2).
        - Allergenic manufacturers submitted 16 fewer reports in FY17
        - Blood derivative manufacturers submitted eight more reports in FY17.
        - Licensed in-vitro diagnostic manufacturers submitted 10 fewer reports in FY17.
        - Vaccine manufacturers submitted 62 fewer reports in FY17.

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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] Katherin D. Ellingon, et al. continued decline in blood collection and transfusion in the United States-2015. Transfusion 2017;57;1588-1598.

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

        - Licensed HCT/P manufacturers (351 HCT/P) submitted five more reports in FY17.
    - Manufacturers of 361 HCT/Ps submitted 38 fewer reports in FY17 compared to FY16 (Table 2).
        - Cellular HCT/P manufacturers submitted nine fewer reports in FY17.
        - Tissue HCT/P manufacturers submitted 29 fewer reports in FY17.
- The total number of reporting establishments increased from 1,950 in FY16 to 2,003 in FY17 (Table 2).
    - Compared to FY16, there were 20 fewer licensed blood establishments, 12 fewer unlicensed blood establishments, 53 more transfusion services and 61 more Source Plasma establishments reporting in FY17.
    - Compared to FY16, there were two more allergenic manufacturers, two more blood derivative manufacturers, one less in-vitro diagnostic manufacturer, four more vaccine manufacturers, and the same number of 351 HCT/P manufacturers reporting in FY17.
    - Compared to FY16, there were 12 fewer 361 HCT/P manufacturers reporting in FY17.

Each firm responsible for reporting BPDs and/or HCT/P 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
FY17

Table 1

Establishment Type	**Number Of Reporting Establishments**	**Total Reports Received**	***Potential* Recalls**[3]	
			#Reports	% *Potential* Recall
Blood/Source Plasma Manufacturers				
Licensed Blood Establishments	206 (*87)	17,956	526	2.9%
Unlicensed Blood Establishments[1]	381	3,298	14	0.4%
Transfusion Services[2]	697	2,080	0	0.0%
Source Plasma Establishments	567(*23)	28,100	57	0.2%
Sub-Total	*1,851*	*51,434*	*597*	1.2%
Licensed Non-Blood Manufacturers				
Allergenic	7 (*7)	73	1	1.4%
Blood Derivative	23 (*19)	142	3	2.1%
In-Vitro Diagnostic	10 (*10)	134	3	2.2%
Vaccine	17 (*15)	203	1	0.5%
351 HCT/P	5(*3)	24	0	0.0%
Sub-Total	*62 (*54)*	*576*	*8*	1.4%
361 HCT/P Manufacturers				
Cellular HCT/P	48	125	0	0.0%
Tissue HCT/P	42	96	26	27.1%
Sub-Total	*90*	*221*	*26*	11.8%
Total	**2,003**	**52,231**	**631**	**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
FY15 – FY17

Table 2

Establishment Type	Number Of Reporting Establishments			Total Reports Received			*Potential* Recalls		
	FY15	**FY16**	**FY17**	**FY15**	**FY16**	**FY17**	**FY15**	**FY16**	**FY17**
Blood/Source Plasma Manufacturers									
Licensed Blood Establishments	219 (96*)	226 (98*)	206 (87*)	18,660	18,664	17,956	486	467	526
Unlicensed Blood Establishments[1]	388	393	381	3,093	3,575	3,298	14	23	14
Transfusion Services[2]	669	644	697	1,826	1,956	2,080	2	0	0
Source Plasma Establishments	462 (21*)	506 (20*)	567 (23*)	22,194	26,124	28,100	67	96	57
Sub-Total	*1,738*	*1,769*	*1,851*	*45,773*	*50,319*	*51,434*	*569*	*586*	*597*
Licensed Non-Blood Manufacturers									
Allergenic	9 (9*)	6 (6*)	7 (7*)	82	89	73	4	4	1
Blood Derivative	25 (20*)	30 (23*)	23 (19*)	123	134	142	1	5	3
In Vitro Diagnostic	9 (9*)	14 (14*)	10 (10*)	111	144	134	4	0	3
Vaccine	24 (18*)	24 (18*)	17 (15*)	223	265	203	2	0	1
351 HCT/P	5 (3*)	5 (4*)	5 (3*)	19	19	24	0	0	0
Sub-Total	*72 (59*)*	*79 (65*)*	*62 (54*)*	*558*	*651*	*576*	*11*	*9*	*8*
361 HCT/P Manufacturers									
Cellular HCT/P	47	55	48	134	134	125	0	0	0
Tissue HCT/P	50	47	42	122	125	96	25	17	26
Sub-Total	*97*	*102*	*90*	*256*	*259*	*221*	*25*	*17*	*26*
Total	**1,907**	**1,950**	**2,003**	**46,587**	**51,229**	**52,231**	**605**	**612**	**631**

[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
FY15 – FY17

Table 3

Manufacturing System	**FY15**		**FY16**		**FY17**	
Donor Eligibility	34,098	74.5%	37,295	74.1%	38,378	74.6%
Post Donation Information	*32,729*	*71.5%*	*35,618*	*70.8%*	*37,265*	*72.5%*
Donor Screening	*1,328*	*2.9%*	*1,628*	*3.2%*	*1,070*	*2.1%*
Donor Deferral	*41*	*0.1%*	*49*	*0.1%*	*43*	*0.1%*
Quality Control & Distribution	4,422	9.7%	5,140	10.2%	4,869	9.5%
Miscellaneous	3,680	8.0%	4,179	8.3%	4,343	8.4%
Labeling	1,638	3.6%	1,717	3.4%	1,825	3.5%
Collection	928	2.0%	903	1.8%	949	1.8%
Laboratory Testing	802	1.8%	841	1.7%	820	1.6%
Routine Testing	*794*	*1.7%*	*827*	*1.6%*	*777*	*1.5%*
Transfusion-Transmitted Infection Testing	*8*	*<0.1%*	*14*	*<0.1%*	*43*	*0.1%*
Component Preparation	205	0.4%	244	0.5%	250	0.5%
Total	**45,773**	**100%**	**50,319**	**100%**	**51,434**	**100%**

Blood & Source Plasma BPD Reports by Manufacturing System FY15 – FY17

Table 4

Manufacturing System	Licensed Blood Establishments			Unlicensed Blood Establishments		
	FY15	FY16	FY17	FY15	FY16	FY17
DE-Post Donation Information	13,474	12,978	12,792	313	326	243
Quality Control & Distribution	1,122	1,215	1,199	1,660	2,005	1,816
Miscellaneous	1,143	1,370	1,297	17	14	8
Labeling	482	435	471	727	807	836
DE-Donor Screening	1,158	1,390	860	25	55	36
Blood Collection	868	877	918	56	21	22
LT-Routine Testing	232	193	179	236	270	265
Component Preparation	150	169	179	52	69	63
DE-Donor Deferral	25	24	25	5	7	2
LT- Transfusion-Transmitted Infection Testing	6	13	36	2	1	7
Total	**18,660**	**18,664**	**17,956**	**3,093**	**3,575**	**3,298**

DE-Donor Eligibility
LT-Laboratory Testing

Table 4 (continued)

Manufacturing System	Transfusion Services			Source Plasma Establishments			Total		
	FY15	FY16	FY17	FY15	FY16	FY17	FY15	FY16	FY17
DE-Post Donation Information	NA	NA	NA	18,942	22,314	24,230	32,729	35,618	37,265
Quality Control & Distribution	1,073	1,147	1,228	567	773	626	4,422	5,140	4,869
Miscellaneous	NA	NA	NA	2,520	2,795	3,038	3,680	4,179	4,343
Labeling	424	440	514	5	35	4	1,638	1,717	1,825
DE-Donor Screening	NA	NA	NA	145	183	174	1,328	1,628	1,070
Blood Collection	NA	NA	NA	4	5	9	928	903	949
LT-Routine Testing	326	364	333	0	0	0	794	827	777
Component Preparation	3	5	5	0	1	3	205	244	250
DE-Donor Deferral	NA	NA	NA	11	18	16	41	49	43
LT- Transfusion-Transmitted Infection Testing	NA	NA	NA	0	0	0	8	14	43
Total	**1,826**	**1,956**	**2,080**	**22,194**	**26,124**	**28,100**	**45,773**	**50,319**	**51,434**

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

Licensed Non-Blood Deviation Reports by Manufacturing System FY15 – FY17

Table 5

Manufacturing System	Allergenic			Blood Derivative			In-Vitro Diagnostic		
	FY15	FY16	FY17	FY15	FY16	FY17	FY15	FY16	FY17
Product Specifications	69	71	67	35	57	70	66	97	88
Quality Control & Distribution	0	1	2	22	18	10	20	29	26
Labeling	6	11	2	2	11	16	14	4	11
Process Controls	2	2	0	27	18	21	3	4	3
Testing	4	4	2	23	13	13	3	6	5
Miscellaneous	0	0	0	7	2	1	1	1	1
Incoming Material	1	0	0	7	15	11	4	3	0
Total	**82**	**89**	**73**	**123**	**134**	**142**	**111**	**144**	**134**

Table 5 (continued)

Manufacturing System	Vaccine			351 HCT/P			Total		
	FY15	FY16	FY17	FY15	FY16	FY17	FY15	FY16	FY17
Product Specifications	74	103	71	8	2	8	252	330	304
Quality Control & Distribution	30	46	41	0	0	0	72	94	79
Labeling	22	17	17	8	14	12	52	57	58
Process Controls	20	40	20	1	0	1	53	64	45
Testing	43	21	24	2	3	1	75	47	45
Miscellaneous	20	25	26	0	0	0	28	28	28
Incoming Material	14	13	4	0	0	2	26	31	17
Total	**223**	**265**	**203**	**19**	**19**	**24**	**558**	**651**	**576**

361 HCT/P Deviation Reports by Manufacturing System FY15 – FY17

Table 6

Manufacturing System	Cellular HCT/Ps			Tissue HCT/Ps			Total		
	FY15	FY16	FY17	FY15	FY16	FY17	FY15	FY16	FY17
Receipt, Pre-Distribution, Shipment & Distribution	48	37	86	21	22	31	69	59	117
Processing & Processing Controls	71	75	26	5	13	3	76	88	29
Donor Eligibility	0	0	1	39	53	28	39	53	29
Donor Testing	2	1	3	9	16	12	11	17	15
Supplies and Reagents	6	5	8	1	3	4	7	8	12
Donor Screening	0	7	0	35	13	11	35	20	11
Labeling Controls	0	0	0	5	0	3	5	0	3
Recovery	7	7	0	3	3	3	10	10	3
Storage	0	2	0	4	1	1	4	3	1
Environmental Control	0	0	1	0	0	0	0	0	1
Equipment	0	0	0	0	1	0	0	1	0
Total	**134**	**134**	**125**	**122**	**125**	**96**	**256**	**259**	**221**

II. BPD Reports Submitted by Blood and Source Plasma Establishments:

General Overview

Blood and Source Plasma establishments submitted 1,115 more reports in FY17 than in the previous fiscal year (FY16-50,319) (Table 2). In FY17, 98% of the total reports submitted were submitted by Blood and Source Plasma establishments.

- **Licensed blood establishments** submitted 708 fewer reports in FY17 than in the previous fiscal year (FY16-18,664) (Table 4); in FY17, 35% of the Blood and Source Plasma reports were submitted by licensed blood establishments.
    - There were 186 fewer reports involving post donation information than in the previous fiscal year (FY16-12,978, FY17-12,792).
        - In FY17, 71% of the reports submitted involved post donation information (FY16-70%).
    - There were 73 fewer reports involving miscellaneous deviations or unexpected events than in the previous fiscal year (FY16-1,370, FY17-1,297).
        - In FY17, 7% of the reports submitted involved miscellaneous deviations or unexpected events (FY16-7%).
    - There were 16 fewer reports involving quality control and distribution than in the previous fiscal year (FY16-1,215, FY17-1,199).
        - In FY17, 7% of the reports submitted involved quality control and distribution (FY16-7%).
    - There were 530 fewer reports involving donor screening than in the previous fiscal year (FY16-1,390, FY17-860).
        - In FY17, 5% of the reports submitted involved donor screening (FY16-7%)
    - There were 41 more reports involving blood collection than in the previous fiscal year (FY16-877, FY17-918).
        - In FY17, 5% of the reports submitted involved blood collection (FY16-5%).
    - The following events represented approximately 5% of the reports submitted by licensed blood establishments in FY17 (total FY16-4%, FY17-5%):
        - There were 36 more reports involving labeling than in the previous fiscal year (FY16-435, FY17-471).
        - There were 23 more reports involving transfusion-transmitted infection testing than in the previous fiscal year (FY16-13, FY17-36).
            - There were 30 reports in which testing was not performed in accordance with the manufacturer's instructions:
                - Ten reports involved syphilis testing.
                - Seven reports involved West Nile Virus testing.
                - Six reports involved bacterial detection testing; in FY16, these events were captured under Quality Control and Distribution.
        - There were 10 more reports involving component preparation than in the previous fiscal year (FY16-169, FY17-179).

        - There were 14 fewer reports involving routine testing than in the previous fiscal year (FY16-193, FY17-179).
        - The number of reports involving donor deferral was similar to the number of reports submitted in the previous year (FY16-24, FY17-25).
- **Unlicensed registered blood establishments** submitted 277 fewer reports in FY17 than in the previous fiscal year (FY16-3,575) (Table 4). In FY17, 6% of the Blood and Source Plasma reports were submitted by unlicensed registered blood establishments.
    - There were 189 fewer reports involving quality control and distribution than in the previous fiscal year (FY16-2,005 FY17-1,816).
        - In FY17, 55% of the reports submitted involved quality control and distribution (FY16-55%).
    - There were 29 more reports involving labeling than in the previous fiscal year (FY16-807, FY17-836).
        - In FY17, 25% of the reports submitted involved labeling (FY16-23%).
    - There were five fewer reports involving routine testing than in the previous fiscal year (FY16-270, FY17-265).
        - In FY17, 8% of the reports submitted involved routine testing (FY16-8%).
    - There were 83 fewer reports involving post donation information than in the previous fiscal year (FY16-326, FY17-243).
        - In FY17, 7% of the reports submitted involved post donation information (FY16-9%).
    - The following events represented approximately 5% of the reports submitted by unlicensed registered blood establishments in FY17 (total FY16-5%, FY17-4%):
        - There were six more reports involving transfusion-transmitted infection testing than in the previous fiscal year (FY16-one; FY17-seven).
        - There were 19 fewer reports involving donor screening than in the previous fiscal year (FY16-55, FY17-36).
        - There were six fewer reports involving component preparation than in the previous fiscal year (FY16-69, FY17-63).
        - There were six fewer reports involving miscellaneous deviations or unexpected events than in the previous fiscal year (FY16-14, FY17-8).
        - There were five fewer reports involving donor deferral than in the previous fiscal year (FY16-seven, FY17-two).
        - The number of reports involving blood collection was similar to the number of reports submitted in the previous year (FY16-21, FY17-22).
- **Transfusion services** submitted 124 more reports in FY17 information than in the previous fiscal year (FY16-1,956) (Table 4); in FY17, 4% of the Blood and Source Plasma reports were submitted by transfusion service.
    - Transfusion services typically report few BPDs and may file no reports in a given year; for example, 456 (65%) of those reporting in FY17 submitted one or two reports and only 84 (12%) transfusion services submitted more than five reports during FY17.
    - There were 81 more reports involving quality control and distribution than in the previous fiscal year (FY16-1,147, FY17-1,228).

        - In FY17, 59% of the reports submitted involved quality control and distribution (FY16-59%)
    - There were 74 more reports involving labeling than in the previous fiscal year (FY16-440, FY17-514).
        - In FY17, 25% of the reports submitted involved labeling (FY16-22%)
    - There were 31 fewer reports involving routine testing than in the previous fiscal year (FY16-364, FY17-333).
        - In FY17, 16% of the reports submitted involved routine testing (FY16-19%)
    - The number of reports involving component preparation was the same as the number of reports submitted in the previous fiscal year (FY16-5, FY17-5).
- **Source Plasma establishments** submitted 1,976 more reports in FY17 than in the previous fiscal year (FY16-26,124) (Table 4); in FY17, 55% of the Blood and Source Plasma reports were submitted by Source Plasma establishments. There were approximately 56 new locations licensed after FY16.
    - There were 1,916 more reports involving post donation information than in the previous fiscal year (FY16-22,314, FY17-24,230).
        - In FY17, 86% of the reports submitted involved post donation information (FY16-85%).
    - There were 243 more reports involving miscellaneous deviations or unexpected events than in the previous fiscal year (FY16-2,795, FY17-3,038).
        - In FY17, 11% of the reports submitted involved miscellaneous deviations or unexpected events (FY16-11%).
    - There were 147 fewer reports involving quality control and distribution than in the previous fiscal year (FY16-773, FY17-626).
        - In FY17, 2% of the reports submitted involved quality control and distribution (FY16-3%).
    - The following events represented less than 5% of the report submitted by Source Plasma establishments in FY17 (total FY16-1%, FY1-1%).
        - There were four more reports involving collection than in the previous fiscal year (FY16-five, FY17-nine).
        - There were 31 fewer reports involving labeling than in the previous fiscal year (FY16-35, FY17-four).
        - There were nine fewer reports involving donor screening than in the previous fiscal year (FY16-183, FY17-174).
        - The number of reports involving donor deferral was similar to the number of reports submitted in the previous fiscal year (FY16-18, FY17-16).
        - The number of reports involving component preparation was similar to the number of reports submitted in the previous fiscal year (FY16-1, FY17-3).
        - There were no reports involving transfusion-transmitted infection testing submitted in FY16 or FY17.

Total BPDRs by Manufacturing System
Blood and Source Plasma Establishments
FY17

Table 7

Manufacturing System	Licensed Blood Establishments	Unlicensed Blood Establishments	Transfusion Services	Source Plasma Establishments	Total	
DE-Post Donation Information	12,792	243	NA	24,230	**37,265**	72.5%
Quality Control & Distribution	1,199	1,816	1,228	626	**4,869**	9.5%
Miscellaneous	1,297	8	NA	3,038	**4,343**	8.4%
Labeling	471	836	514	4	**1,825**	3.6%
DE-Donor Screening	860	36	NA	174	**1,070**	2.1%
Blood Collection	918	22	NA	9	**949**	1.8%
LT-Routine Testing	179	265	333	0	**777**	1.5%
Component Preparation	179	63	5	3	**250**	0.5%
DE-Donor Deferral	25	2	NA	16	**43**	0.1%
LT-Transfusion-Transmitted Infection Testing	36	7	NA	0	**43**	0.1%
Total	**17,957**	**3,298**	**2,080**	**28,100**	**51,434**	100%

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

Post Donation Information

Post donation information continues to be the most frequently reported event associated with the manufacturing of Blood and Source Plasma products (72% of deviation reports) (Tables 3 and 7). The number of reports Blood and Source Plasma establishments submitted involving post donation information increased 5% from the previous fiscal year (FY16-35,618, FY17-37,266) (Table 4).

- **Blood establishments** submitted 269 fewer reports involving post donation information in FY17 compared to FY16, which is a decrease of 2% (Table 8).
    - They submitted 52 fewer reports involving a donor who traveled to a malarial risk area, 55 more reports involving a donor who traveled to a variant Creutzfeldt-Jakob Disease (vCJD) risk area, 364 more reports involving a donor who received a tattoo and/or piercing, and 16 more reports involving a donor with a history of taking finasteride, Tegison, Accutane, or Avodart, Jalyn, or Absorica, and 516 fewer reports involving a male donor who had a history of sex with another male in FY17 compared to FY16.
- **Source Plasma establishments** submitted 1,916 more reports involving post donation information in FY17 compared to FY16, which is an increase of 9% (Table 8).
    - They submitted 1,882 more reports involving a donor who had a history of tattoo and/or piercing, 254 more reports involving a donor who tested positive for a viral marker at another center, and 328 fewer reports involving a donor who had a history of incarceration in FY17 compared to FY16.

Table 8 illustrates the major differences in post donation information reports from FY15 to FY17. Only the five most frequently reported categories are included in the table.

Post Donation Information Reports Submitted by Blood and Source Plasma Establishments - FY15-FY17

Table 8

Blood Establishments	**FY15**	**FY16**	**FY17**
Post Donation Information (PD) – *total*	13,787	13,304	13,035
Donor had a history of travel to malarial risk area (PD1236)	4,223	4,184	4,132
Donor had a history of travel to vCJD risk area (PD1242)	2,393	2,102	2,157
Donor received tattoo and/or piercing (PD1259)	973	845	1,209
Donor received finasteride, Tegison, Accutane, or Avodart, Jalyn, or Absorica (PD1245)	761	880	896
Donor had history of male to male sex (PD1214)	922	942	426
Source Plasma Establishments			
Post Donation Information (PD) – *total*	18,942	22,314	24,230
Donor received tattoo and/or piercing (PD1259)	12,975	14,115	15,997
Donor tested reactive at another center, specific testing unknown (PD1114)	1,116	1,681	1,935
Donor had a history of incarceration (PD1249)	844	1,187	859
Intimate contact with risk for a relevant transfusion-transmitted infection – Hepatitis C Virus (PD1264)	666	668	802

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

Miscellaneous

The total number of miscellaneous reports submitted in FY17 increased 4% from the previous fiscal year (FY16-4,179, FY17-4,344) (Table 3). Most 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 (FY16-4,155, FY17-4,212).

- The number of these reports submitted by **blood establishments** in FY17 decreased 7% from the previous fiscal year (FY16-1,360, FY17-1,277) (Table 9).
- The number of these reports submitted by **Source Plasma establishments** in FY17 increased 9% from the previous fiscal year (FY16-2,795, FY17-3,038) (Table 9).

Table 9 illustrates the number of reports from FY13 to FY17 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
FY13-FY17

Table 9

Blood Establishments	**FY13**	**FY14**	**FY15**	**FY16**	**FY17**
Lookback; Subsequent unit confirmed positive (MI02) - *total*	1,140	1,202	1,132	1,360	1,277
HCV (MI0204)	470	421	321	319	316
HBV (MI0203)	343	412	568	435	169
HIV (MI0202)	200	191	129	123	132
Source Plasma Establishments					
Lookback; Subsequent unit confirmed positive (MI02) - *total*	2,093	2,523	2,520	2,795	3,038
HCV (MI0204)	1,435	1,643	1,677	1,806	1,946
HBV (MI0203)	390	578	508	593	641
HIV (MI0202)	264	296	316	391	447

HCV – Hepatitis C Virus
HBV – Hepatitis B Virus
HIV – Human Immunodeficiency Virus

A. Most Frequent BPD Reports Submitted by Licensed Blood Establishments[5]

Of the 17,956 reports (Table 7) submitted by licensed blood establishments in FY17, 12,792 reports (71.2%) involved **post donation information** (Table 10).

- The number of these reports decreased 1% from the previous fiscal year (FY16-12,978).
- The number of reports in which a donor or third party provided subsequent information related to high risk behavior or history decreased 1% from the previous fiscal year (FY16-11,908).
    - The number of reports in which a donor or third party provided subsequent information regarding male to male sex decreased 54% from the previous fiscal year (FY16-923).
    - The number of reports in which a donor or third party provided subsequent information regarding travel to a malaria risk area decreased from 4,079 in FY16 to 4,052 in FY17.
    - The number of reports in which a donor or third party provided subsequent information regarding received a tattoo and/or piercing increased 44% from the previous fiscal year (FY16-829).
    - The number of reports in which a donor or third party provided subsequent information regarding travel to a vCJD risk area increased 4% from the previous fiscal year (FY16-2,030).
    - The number of reports in which a donor or third party provided subsequent information regarding receiving finasteride, Tegison, Accutane, Avodart, Jalyn, or Absorica increased from 858 in FY16 to 877 in FY17.
- The number of reports in which a donor or third party provided subsequent information related to a post donation illness decreased 4% from the previous fiscal year (FY16-932).
    - The number of reports in which a donor had a fever or diarrhea post donation decreased 7% from the previous fiscal year (FY16-459).
    - The number of reports in which a donor had an infection post donation increased from 242 in FY16 to 251 in FY17.
- The number of reports in which a donor or third party provided subsequent information related to the donor testing positive decreased from 102 in FY16 to 92 in FY17.

[5] 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* FY17

Table 10

POST DONATION INFORMATION (PD) 12,792	# Reports	% of Total (PD)
Behavior/History	***11,779***	***92.1%***
Travel to malaria endemic area/history of malaria	4,052	31.7%
Risk factors associated with vCJD – travel	2,111	16.5%
Donor received tattoo and/or piercing	1,195	9.3%
Received finasteride (Proscar or Propecia), Tegison, Accutane, Avodart, Jalyn, or Absorica	877	6.9%
Received medication or antibiotics	501	3.9%
Male donor had sex with another man	421	3.3%
Illness	***891***	***7.0%***
Post donation illness (not hepatitis, HIV, cancer or cold/flu related)	817	6.4%
Fever/diarrhea	427	3.3%
Infection	251	2.0%
Post donation diagnosis or symptoms of Hepatitis C, or reactive test for Hepatitis C	23	0.2%
Post donation diagnosis or symptoms of HIV, or reactive test for HIV	20	0.2%
Post donation diagnosis or possible diagnosis of CJD	10	0.1%
Post donation diagnosis or symptoms of sexually transmitted disease, or reactive test for sexually transmitted disease	10	0.1%
Testing *	***92***	***0.7%***
Tested reactive for HIV prior to donation	33	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 at another center, specific testing unknown	10	0.1%
Not specifically related to high risk behavior	***30***	***0.2%***
Donor does not want their blood used	22	0.2%
Donated to be tested or called back for test results	7	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 17,956 reports (Table 7) submitted by licensed blood establishments in FY17, 1,297 reports (7.2%) involved **miscellaneous** deviations or unexpected events (Table 11)**.**

- The number of these reports decreased 5% from the previous fiscal year (FY16-1,370).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for a viral marker decreased 6% from the previous fiscal year (FY16-1,347).
    - The number of reports in which a donor subsequently tested confirmed positive for HCV was the same as the number of reports submitted in the previous year (FY16-316).
    - The number of reports in which a donor subsequently tested confirmed positive for HIV increased from 124 in FY16 to 135 in FY17.
    - The number of reports in which a donor subsequently tested confirmed positive for HBV decreased 60% from the previous fiscal year (FY16-431).
        - The number of reports in which a donor tested repeat reactive on two occasions for anti-Hepatitis B core (HBc), decreased 74% from the previous fiscal year (FY16-369).
    - The number of reports in which a donor subsequently tested positive {using an Investigational New Drug (IND) test} for Babesia increased 26% from the previous fiscal year (FY16-384).
- 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 (FY16-23, FY17-27).
    - There were 17 reports submitted in FY17 (FY16-18) involving Babesia; in one case, the donor was not ruled out.
    - There were two reports involving Hepatitis C submitted in FY17 (FY16-2); in both cases, the donor was not ruled out.
    - There were two reports involving malaria submitted in FY17 (FY16-0).

Most Frequent BPD Reports - Miscellaneous From *Licensed Blood Establishments* FY17

Table 11

MISCELLANEOUS (MI) 1,297	# Reports	% of Total (MI)
Lookback; subsequent unit tested confirmed positive for:	***1,270***	***97.9%***
Babesia	484	37.3%
HCV	316	24.4%
HBV	172	13.3%
Anti-HBc positive	95	7.3%
HIV	135	10.4%
Zika Virus	92	7.1%
West Nile Virus	64	4.9%
Donor implicated in transfusion associated disease	***27***	***2.1%***
Babesia	17	1.3%
Hepatitis C	2	0.2%
Malaria	2	0.2%
West Nile Virus	1	0.1%

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

Of the 17,956 reports (Table 7) submitted by licensed blood establishments in FY17, 1,199 reports (6.7%) involved **quality control and distribution** deviations or unexpected events (Table 12).

- The number of these reports decreased 1% from the previous fiscal year (FY16-1,215).
- The number of reports involving the distribution of a product that did not meet specifications decreased 35% from the previous fiscal year (FY16-790); in FY17, events associated with bacterial detection testing were not captured with these events.
    - The number of reports involving the release of a product in which product quality control was unacceptable, not performed, not documented, or incomplete decreased from 557 in FY16 to 297 in FY17 (47%).
        - The number of reports related to bacterial detection testing decreased from 305 in FY16 to 283 in FY17; in FY17, these events were captured under BPD Codes specific to either a positive test (QC-92-16), testing not performed or incompletely performed (QC-93-18), or performed or documented incorrectly (VT-71-19).
- The number of reports involving shipping and storage was similar to the number of reports submitted in the previous fiscal year (FY16, FY17-167).
- The number of reports involving distribution procedures not performed in accordance with blood bank transfusion service's specification decreased from 143 in FY16 to 91 in FY17.

Most Frequent BPD Reports - Quality Control & Distribution
From *Licensed Blood Establishments*
FY17

Table 12

QUALITY CONTROL & DISTRIBUTION (QC) 1,199	# Reports	% of Total (QC)
Distribution of product that did not meet specifications	***514***	***42.9%***
Product QC unacceptable, not performed, not documented, or incomplete	297	24.8%
White Blood Cell count	100	8.3%
Platelet count	83	6.9%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or documented	44	3.7%
Product identified as unsuitable due to a collection deviation or unexpected event	39	3.3%
Product identified as unsuitable due to a donor screening deviation or unexpected event	27	2.3%
Positive testing	***327***	***27.3%***
Bacterial detection testing	244	20.4%
Shipping and storage	***167***	***13.9%***
Product not packaged in accordance with specifications or no documentation that product was packed appropriately	53	4.4%
Product arrived at consignee at unacceptable temperature	32	2.7%
No documentation that product was shipped or stored at appropriate temperature	23	1.9%
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***91***	***7.6%***
Improper product selected for patient	22	1.8%
Product not irradiated as required	17	1.4%
Product not documented or incorrectly documented as issued in the computer	13	1.1%
Testing not performed, incompletely performed, or not documented	***88***	***7.3%***
Bacterial detection testing	39	3.3%
Chagas	16	1.3%
HLA antibodies	12	1.0%

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

Of the 17,956 (Table 7) reports submitted by licensed blood establishments in FY17, 918 reports (5.1%) involved **blood collection** deviations or unexpected events (Table 13)**.**

- The number of these reports increased 5% from the previous fiscal year (FY16-877).
- The number of reports involving the collection process increased 8% from the previous fiscal year (FY16-760).
    - The number of reports involving clotted units increased 9% from the previous fiscal year (FY16-726).
    - The number of reports in which the sterility of a product may have been compromised decreased from 107 in FY16 to 90 in FY17.
        - The number of reports involving bacterial contamination, discovered as a result of a patient transfusion reaction, decreased from 80 in FY16 to 69 in FY17; the most common organisms identified were *Staphylococcus epidermidis,* coagulase-negative staphylococci, and other staphylococcus species.

Most Frequent BPD Reports – Blood Collection From *Licensed Blood Establishments* FY17

Table 13

BLOOD COLLECTION (BC) 918	#Reports	% of Total (BC)
Collection process	***821***	***89.4%***
Product contained clots or fibrin, not discovered prior to distribution	790	86.1%
Product hemolyzed, not discovered prior to distribution	12	1.3%
Donor sample tube mix-up or donor sample tube mislabeled	7	0.8%
Apheresis collection process	4	0.4%
Sterility compromised	***90***	***9.8%***
Bacterial contamination	69	7.5%
Arm prep not performed or performed inappropriately	13	1.4%
Air contamination	6	0.7%
Collection bag	***5***	***0.5%***
Potential collection set defect	4	0.4%

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

Of the 17,956 reports (Table 7) submitted by licensed blood establishments in FY17, 860 reports (4.8%) involved **donor screening** deviations or unexpected events (Table 14).

- The number of these reports decreased 38% from the previous fiscal year (FY16-1,390).
- 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 decreased 49% from the previous fiscal year (FY16-906).
    - In FY17, 74% of these reports involve donors who were not previously deferred.
- The number of reports in which the donor record was incomplete or incorrect decreased 19% from the previous fiscal year (FY16-278).
    - In FY17, 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 187 in FY16 to 149 in FY17.

Most Frequent BPD Reports - Donor Screening
From *Licensed Blood Establishments*
FY17

Table 14

DONOR SCREENING 860	# Reports	% of Total (DS)
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***458***	***53.3%***
Donor not previously deferred	337	39.2%
Donor previously deferred due testing	61	7.1%
Donor previously deferred due to history	60	7.0%
Donor record incomplete or incorrect	***226***	***26.3%***
Donor history questions	205	23.8%
Incorrect gender specific question asked or incorrect answer	160	18.6%
Donor identification	11	1.3%
Donor gave history which warranted deferral or follow up and was not deferred	***149***	***17.3%***
Travel to malaria endemic area/history of malaria	72	8.4%
Risk factors associated with vCJD - travel	42	4.9%
Donor did not meet acceptance criteria	***25***	***2.9%***
Hemoglobin or Hematocrit unacceptable or not documented or testing was performed incorrectly	14	1.6%
Medical review or physical not performed or inadequate	5	0.6%

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

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

Of the 3,298 reports (Table 7) submitted by unlicensed registered blood establishments, 1,816 reports (55.1%) involved **quality control and distribution** deviations or unexpected events (Table 15)**.**

- The number of these reports decreased 9% from the previous fiscal year (FY16-2,005).
- The number of reports involving distribution procedures not performed in accordance with the blood bank transfusion service's specifications decreased 13% from the previous fiscal year (FY16-1,655).
    - 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, decreased 20% from the previous fiscal year (FY16-803).
    - The number of reports involving the product not irradiated as required decreased from 196 in FY16 to 180 in FY17.
- The number of reports involving testing that was not performed, incompletely performed, or not documented increased from 169 in FY16 to 214 in FY17, which included an increase of reports involving bacterial detection testing (FY16-18, FY17-32).

Most Frequent BPD Reports - Quality Control & Distribution From *Unlicensed Registered Blood Establishments* FY17

Table 15

QUALITY CONTROL & DISTRIBUTION (QC) 1,816	# Reports	% of Total (QC)
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***1,442***	***79.4%***
Product not documented or incorrectly documented as issued in the computer	645	35.5%
Product not irradiated as required	180	9.9%
Improper product selected for patient	174	9.6%
Improper ABO or Rh type selected for patient	142	7.8%
Procedure for issuing not performed or documented in accordance with specifications	87	4.8%
Testing not performed, incompletely performed, or not documented	***214***	***11.8%***
Antibody screen or identification	57	3.1%
Antigen screen	39	2.1%
ABO and/or Rh	32	1.8%
Bacterial testing	32	1.8%
Distribution of product that did not meet specifications	***113***	***6.2%***
Product in which instrument QC, calibration, or validation unacceptable, incomplete or not documented	32	1.8%
Product in which specification other than QC not met	25	1.4%
Outdated product	21	1.2%
Shipping and storage	***40***	***2.2%***
Temperature not recorded or unacceptable upon return, unit redistributed	13	0.7%
No documentation that product was shipped or stored at appropriate temperature	10	0.6%

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

Of the 3,298 reports (Table 7) submitted by unlicensed registered blood establishments in FY17, 836 reports (25.3%) involved **labeling** deviations or unexpected events (Table 16).

- The number of these reports increased 4% from the previous fiscal year (FY16-807).
- The number of reports involving the crossmatch tag, tie tag, or transfusion record labeled with incorrect or missing information increased 5% from the previous fiscal year (FY16-550).
    - The number of reports involving the recipient identification incorrect or missing increased from 133 in FY16 to 161 in FY17.
    - The number of reports involving the crossmatch tags or transfused records switched, but both units were intended for the same patient decreased from 163 in FY16 to 155 in FY17.
- The number of reports involving the unit labeled with incorrect or missing information was the same as in the previous year (FY16-257).
    - The number of reports involving the expiration date extended or missing on the product label decreased from 110 in FY16 to 91 in FY17.
    - There were 30 reports involving the incorrect or missing test status for the Zika virus test in FY17; these events were not reported in the previous year because testing was not performed.

Most Frequent BPD Reports - Labeling
From *Unlicensed Registered Blood Establishments*
FY17

Table 16

LABELING (LA) 836	#Reports	% of Total (LA)
Crossmatch tag, tie tag, to transfusion record incorrect or missing information	***579***	***69.3%***
Recipient identification incorrect or missing	161	19.3%
Crossmatch tags or transfused records switched, both units intended for the same patient	155	18.5%
Crossmatch tag, tie tag, or transfusion record incorrect or missing or attached to incorrect unit	57	6.8%
Unit, lot, or pool number incorrect or missing	39	4.7%
Expiration date or time extended or missing	37	4.4%
Product type or code incorrect or missing	30	3.6%
Labels applied to blood unit or product incorrect or missing information	***257***	***30.7%***
Extended or missing expiration date or time	91	10.9%
Product type or code incorrect or missing	46	5.5%
Irradiation status incorrect or missing	35	4.2%
Zika virus test status incorrect or missing	30	3.6%
Combination of incorrect or missing information	16	1.9%
Product or anticoagulant volume or weight incorrect or missing	14	1.7%

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

Of the 3,298 reports (Table 7) submitted by unlicensed registered blood establishments in FY17, 265 reports (8.0%) involved **routine testing** deviations or unexpected events (Table 17).

- The number of these reports decreased from 270 in FY16 to 265 in FY17.
- The number of reports involving testing performed, interpreted or documented incorrectly decreased from 159 in FY16 to 149 in FY17.
- The number of reports involving sample identification was similar to the number of reports submitted the previous year (FY16- 49, FY17-51).
- The number of reports involving unacceptable reagent quality control or the use of expired reagents was similar to the number of reports submitted the previous year (FY16-62, FY17-65).

Most Frequent BPD Reports - Routine Testing From *Unlicensed Registered Blood Establishments* FY17

Table 17

ROUTINE TESTING (RT) 265	# Reports	% of Total (RT)
Testing performed, interpreted, or documented incorrectly	***149***	***56.2%***
Compatibility	63	23.8%
Antibody screening or identification	40	15.1%
ABO and/or Rh	23	8.7%
Antigen typing	15	5.7%
Reagent QC unacceptable or expired reagents used	***65***	***24.5%***
Antigen typing	20	7.5%
ABO and/or Rh	19	7.2%
Antibody screening or identification	12	4.5%
Multiple testing	7	2.6%
Sample (used for testing) identification	***51***	***19.2%***
Sample used for testing was incorrectly or incompletely labeled	36	13.6%
Unsuitable sample used for testing (e.g., too old)	8	3.0%
Incorrect sample tested	7	2.6%

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

Of the 3,298 reports (Table 7) submitted by unlicensed registered blood establishments in FY17, 243 reports (7.4%) involved **post donation information** (Table 18)**.**

- The number of these reports decreased 26% from the previous fiscal year (FY16-326).
- The number of reports in which a donor or third party provided subsequent information related to high risk behavior or history decreased from 312 in FY16 to 236 in FY17.
    - The number of reports in which a donor or third party provided subsequent information regarding travel to a malarial risk area decreased from 105 in FY16 to 80 in FY17.
    - The number of reports in which a donor or third party provided subsequent information regarding travel to a vCJD risk area decreased from 72 in FY16 to 46 in FY17.
- The number of reports in which a donor or third party provided subsequent information related to post donation illness decreased from 11 in FY16 to 4 in FY17.

Most Frequent BPD Reports - Post Donation Information From *Unlicensed Registered Blood Establishments* FY17

Table 18

POST DONATION INFORMATION (PD) 243	# Reports	% of Total (PD)
Behavior/History	***236***	***97.1%***
Travel to malaria endemic area/history of malaria	80	32.9%
Risk factors associated with vCJD – travel	46	18.9%
Received finasteride (Proscar or Propecia), Tegison, Accutane, Avodart, Jalyn, or Absorica	19	7.8%
History of disease	18	7.4%
Donor received tattoo and/or piercing	14	5.8%
Illness	***4***	***1.6%***

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

C. Most Frequent BPD Reports Submitted by Transfusion Services

Of the 2,080 reports (Table 7) submitted by transfusion services in FY17, 1,228 reports (59.0%) involved **quality control and distribution** deviations or unexpected events (Table 19).

- The number of these reports increased 7% from the previous fiscal year (FY16-1,147).
- The number of reports involving distribution procedures not performed in accordance with the blood bank transfusion service's specifications increased 12% from the previous fiscal year (FY16-829).
    - 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 12% from the previous fiscal year (FY16-364).
- The number of reports in which testing was not performed, incompletely performed, or not documented decreased 7% from the previous fiscal year (FY16-212).
    - The number of reports in which ABO/Rh typing was not performed, incompletely performed, or not documented was similar to the previous year (FY16-55, FY17-54).
    - The number of reports in which antigen screening was not performed, incompletely performed, or not documented was similar to the previous year (FY16-51, FY17-56).
    - The number of reports in which antibody screening was not performed, incompletely performed, or not documented decreased from 47 in FY16 to 39 in FY17.

Most Frequent BPD Reports - Quality Control & Distribution From *Transfusion Services* FY17

Table 19

QUALITY CONTROL & DISTRIBUTION (QC) 1,228	# Reports	% of Total (QC)
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***929***	***75.7%***
Product not documented or incorrectly documented as issued in the computer	409	33.3%
Product not irradiated as required	128	10.4%
Procedure for issuing not performed or documented in accordance with specifications	98	8.0%
Improper product selected for patient	85	6.9%
Improper ABO or Rh type selected for patient	71	5.8%
Testing not performed, incompletely performed, or not documented	***198***	***16.1%***
Antigen screen	56	4.6%
ABO and/or Rh	54	4.4%
Antibody screen or identification	39	3.2%
Compatibility	35	2.9%
Distribution of product that did not meet specifications	***61***	***5.0%***
Outdated product	27	2.2%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or not documented	12	1.0%
Product identified as unsuitable due to a shipping or storage deviation or unexpected event	5	0.4%
Shipping and storage	***36***	***2.9%***
Stored at incorrect temperature	12	1.0%
No documentation that product was shipped or stored at appropriate temperature	11	0.9%

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

Of the 2,080 reports (Table 7) submitted by transfusion services in FY17, 514 reports (24.7%) involved **labeling** deviations or unexpected events (Table 20)**.**

- The number of these reports increased 17% from the previous fiscal year (FY16-440).
- The number of reports involving the crossmatch, tie tag, or transfusion record labeled with incorrect or missing information increased 18% from the previous fiscal year (FY16-372, FY17-438).
- The number of reports involving the unit labeled with incorrect or missing information increased from 67 in FY16 to 76 in FY17.

Most Frequent BPD Reports - Labeling From *Transfusion Services* FY17

Table 20

LABELING (LA) 514	# Reports	% of Total (LA)
Crossmatch tag, tie tag or transfusion record incorrect or missing information	***438***	***85.2%***
Crossmatch tags or transfused records switched, both units intended for the same patient	98	19.1%
Recipient identification incorrect or missing	125	24.3%
Crossmatch tag or tie tag missing or attached to incorrect unit	54	10.5%
Unit, lot, or pool number incorrect or missing	33	6.4%
Product type or code incorrect or missing	26	5.1%
Antigen incorrect or missing	22	4.3%
Expiration date or time extended or missing	21	4.1%
Labels applied to blood unit or product incorrect or missing information	***76***	***14.8%***
Extended or missing expiration date or time	30	5.8%
Product type/code and expiration date incorrect or missing	16	3.1%
Combination of incorrect or missing information	14	2.7%

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

Of the 2,080 reports (Table 7) submitted by transfusion services in FY17, 333 reports (16.0%) involved **routine testing** deviations or unexpected events (Table 21).

- The number of these reports decreased 9% from the previous fiscal year (FY16-364).
- The number of reports involving testing performed, interpreted, or documented incorrectly decreased from 217 in FY16 to 209 in FY17.
- The number of reports involving unacceptable reagent quality control or the use of expired reagents decreased from 86 in FY16 to 70 in FY17.
- The number of reports involving sample identification decreased from 61 in FY16 to 54 in FY17.

Most Frequent BPD Reports - Routine Testing From *Transfusion Services* FY17

Table 21

ROUTINE TESTING 333	# Reports	% of Total (RT)
Testing performed, interpreted, or documented incorrectly	***209***	***62.8%***
Compatibility	97	29.1%
Antibody screening or identification	55	16.5%
ABO and/or Rh typing	23	6.9%
Antigen typing	20	6.0%
Reagent QC unacceptable or expired reagents used	***70***	***21.0%***
Antigen typing	21	6.3%
Multiple testing	19	5.7%
ABO and/or Rh typing	13	3.9%
Antibody screening or identification	11	3.3%
Sample (used for testing) identification	***54***	***16.2%***
Sample used for testing was incorrectly or incompletely labeled	40	12.0%
Unsuitable sample used for testing	11	3.3%
Incorrect sample tested	2	0.6%

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

D. Most Frequent BPD Reports Submitted by Source Plasma Establishments

Of the 28,100 reports (Table 7) submitted by Source Plasma establishments in FY17, 24,230 reports (86.2%) involved **post donation information** (Table 22)**.**

- The number of these reports increased 9% from the previous fiscal year (FY16-22,314).
- The number of reports in which a donor or third party provided subsequent information related to high risk behavior or history increased 8% from the previous fiscal year (FY16-20,512).
    - The number of reports in which the donor had a history of a tattoo and/or piercing increased 13% from the previous fiscal year (FY16-14,115).
    - The number of reports in which the donor was deferred by another center, but the reason for deferral was unknown increased three-fold from the previous fiscal year (FY16-337); this increase was due to an increase in the number of new Source Plasma locations reporting.
    - The number of reports in which the donor had a history of incarceration decreased 28% from the previous fiscal year (FY16-1,187).
    - The number of reports in which the donor had intimate contact with risk for hepatitis (Hepatitis C or Hepatitis B) increased 12% from the previous fiscal year (FY16-1,075).
        - Hepatitis C: FY16-668, FY17-802
        - Hepatitis B: FY16-407, FY17-407
    - The number of reports in which a donor or third party provided subsequent information related to testing by another facility increased 15% from the previous fiscal year (FY16-1,690); most of these reports involved a donor tested positive by another facility, but the specific testing was unknown (FY16-1,681).

Most Frequent BPD Reports - Post Donation Information From *Source Plasma Establishments* FY17

Table 22

POST DONATION INFORMATION (PD) 24,230	# Reports	% of Total (PD)
Behavior/History	***22,174***	***91.5%***
Donor received tattoo and/or piercing	15,997	66.0%
Donor deferred by another center – reason unknown	901	3.7%
Incarcerated	859	3.5%
Intimate contact with risk for a relevant transfusion-transmitted infection - HCV	802	3.3%
Other (unacceptable address; donor comprehension questionable)	600	2.5%
IV drug use	527	2.2%
Intimate contact with risk for a relevant transfusion-transmitted infection - HBV	407	1.7%
Testing*	***1,941***	***8.0%***
Tested reactive at another center, specific testing unknown	1,935	8.0%
Illness	***72***	***0.3%***
Post donation diagnosis or symptoms of Hepatitis C, or reactive test for Hepatitis C	35	0.1%
Post donation diagnosis or symptoms of HIV, or reactive test for HIV	25	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 28,100 reports (Table 7) submitted by Source Plasma establishments, 3,038 reports (10.8%) involved **miscellaneous** deviations or unexpected events (Table 23).

- The number of these reports increased 9% from the previous fiscal year (FY16-2,795).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for HCV increased 8% from the previous fiscal year (FY16-1,806).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for HBV increased 8% from the previous fiscal year (FY16- 593).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for HIV increased 14% from the previous fiscal year (FY16-391).

Most Frequent BPD Reports - Miscellaneous
From *Source Plasma Establishments*
FY17

Table 23

MISCELLANEOUS (MI) 3,038	# Reports	% of Total (MI)
Lookback; subsequent unit tested confirmed positive for:	***3,038***	***100%***
HCV	1,946	64.0%
HBV	641	21.1%
HIV	447	14.7%
Multiple markers	4	0.1%

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

Of the 28,100 reports (Table 7) submitted by Source Plasma establishments in FY17, 626 reports (2.2%) involved **quality control and distribution** deviations or unexpected events (Table 24**).**

- The number of these reports decreased 19% from the previous fiscal year (FY16-773).
- The number of reports involving the distribution of a product with a positive test decreased from 684 in FY16 to 522 in FY17; 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 increased from 14 in FY16 to 31 in FY17.
- The number of reports involving the distribution of a product that should have been quarantined was similar to the number of reports submitted in the previous year (FY16-73, FY17-71).
    - Fail to quarantine due to medical history (FY16-51, FY17-52).
    - Fail to quarantine due to transfusion-transmitted infection testing deviation (FY16-5, FY17-9).
    - Fail to quarantine due to donor screening deviation (FY16-9, FY17-6).
    - Fail to quarantine due to collection deviation (FY16-5, FY17-2).

Most Frequent BPD Reports - Quality Control & Distribution From *Source Plasma Establishments* FY17

Table 24

QUALITY CONTROL & DISTRIBUTION (QC) 626	# Reports	% of Total (QC)
Positive testing for	***522***	***83.4%***
Antibody screen or identification	521	83.2%
Failure to quarantine unit due to medical history	***52***	***8.3%***
Post Donation Illness	37	5.9%
Donor received tattoo and/or piercing	4	0.6%
Testing not performed, incompletely performed or not documented for	***31***	***5.0%***
Syphilis	17	2.7%
HIV/HCV/HBV Nucleic Acid Test (NAT)	8	1.3%
All viral markers	6	1.0%
Distribution of product that did not meet specifications	***19***	***3.0%***
Product identified as unsuitable due to a transfusion-transmitted infection testing deviation or unexpected event	9	1.4%
Product identified as unsuitable due to a donor screening deviation or unexpected event	6	1.0%
Product identified as unsuitable due to a collection deviation or unexpected event	2	0.3%

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

Of the 28,100 reports (Table 7) submitted by Source Plasma establishments in FY17, 174 reports (0.6%) involved **donor screening** deviations or unexpected events (Table 25).

- The number of these reports decreased 5% from the previous fiscal year (FY16-183).
- The number of reports involving incomplete or incorrect donor records decreased from 97 in FY16 to 78 in FY17.
- The number of reports involving donors who did not meet acceptance criteria increased from 24 in FY16 to 45 in FY17.
- 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 23 in FY16 to 32 in FY17.
- 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 39 in FY16 to 18 in FY17.

Most Frequent BPD Reports - Donor Screening From *Source Plasma Establishments* FY17

Table 25

DONOR SCREENING (DS) 174	# Reports	% of Total (DS)
Donor record incomplete or incorrect	***78***	***44.8%***
Donor identification	41	23.6%
Donor history questions	33	19.0%
Donor did not meet acceptance criteria	***45***	***25.9%***
Medical review or physical not performed or inadequate	38	21.8%
Unacceptable address or no proof of address	6	3.4%
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***32***	***18.4%***
Donor not previously deferred	27	15.5%
Donor previously deferred due to history	5	2.9%
Donor gave history which warranted deferral or follow up and was not deferred	***18***	***10.3%***
Intimate contact with risk for a relevant transfusion-transmitted infection - HCV	7	4.0%
Risk factors associated with vCJD - travel	4	2.3%
Donor received tattoo and/or piercing	3	1.7%

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 75 fewer reports in FY17 than in the previous fiscal year (FY16-651) (Table 2). The number of reports submitted in FY17 by licensed non-blood manufacturers is displayed in Table 26.

- **Allergenic manufacturers** submitted 16 fewer reports compared to the previous fiscal year (FY16-89) (Table 5).
    - The number of reports involving product not meeting specifications was similar to the number of reports submitted in the previous year (FY16-71, FY17-67); the majority (88%) of the total reports related to precipitate discovered in allergenic extracts, which was similar to the number of reports submitted in the previous year (FY16-65, FY17-64).
- **Blood derivative manufacturers** submitted eight more reports compared to the previous fiscal year (FY16-134) (Table 5).
    - The number of reports related to product specifications increased from 57 in FY16 to 70 in FY17.
        - The number of reports involving the failure of stability testing for potency increased from eight in FY16 to 21 in FY17.
        - The number of reports involving product specification not met for appearance was the same as the previous fiscal year (FY16-8).
        - 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 in the previous fiscal year (FY16-14, FY17-17).
    - The number of reports related to process controls was similar to the number of reports submitted in the previous year (FY16-18, FY17-21).
        - The number of reports related to process/procedures not performed or performed incorrectly was similar to the number of reports submitted in the previous year (FY16-14, FY17-16); most of these events were related to equipment not performing properly (FY16-9, FY17-8).
- **In-vitro diagnostic manufacturers** submitted 10 fewer reports compared to the previous fiscal year (FY16-144) (Table 5).
    - The number of reports related to the product specifications decreased from 97 in FY16 to 88 in FY17.
        - The number of reports related to unexpected reactions in testing was similar to the number of reports submitted in the previous fiscal year (FY16-61, FY17-58).
        - The number of reports related to leaking vial or container, due to loose or unsecure closures was similar to the number of reports submitted in the previous fiscal year (FY16-15, FY17-14).
    - The number of reports related to quality control and distribution was similar to the number of reports submitted the previous fiscal year (FY16-29, FY17-26); the number of reports related to the consignee receiving products upside down or sideways within the shipping container was the same as in the previous fiscal year (FY16-15).

- **Vaccine manufacturers** submitted 62 fewer reports compared to the previous fiscal year (FY16-265) (Table 5).
    - The number of reports involving product specifications decreased from 103 in FY16 to 71 in FY17.
        - The number of reports involving product not meeting specifications for appearance decreased from 44 in FY16 to 29 in FY17.
        - The number of reports involving stability failures decreased from 28 in FY16 to 18 in FY17; most of these reports were related to potency (FY16-10, FY17-8).
    - The number of reports involving quality control and distribution was similar to the number of reports submitted in the previous fiscal year (FY16-46, FY17-41).
        - The number of reports involving broken or cracked vials was similar to the number of reports submitted the previous year (FY16-35, FY17-34).
    - The number of reports involving testing was similar to the number of reports submitted in the previous fiscal year (FY16-21, FY17-24); most of these reports were related to stability testing performed incorrectly or not performed (FY16-13, FY17-11).
    - The number of reports involving process controls decreased from 40 in FY16 to 20 in FY17.
- **Licensed HCT/P manufacturers** (351 HCT/Ps) submitted five more reports compared to the previous fiscal year (FY16-19) (Table 5).
    - The number of reports related to the labeling controls was similar to the number of reports submitted in the previous fiscal year (FY16-14, FY17-12); most of these reports involved the product labeled with the incorrect recipient identification (FY16-12, FY17-12).
    - The number of reports involving product specifications increased from two in FY16 to eight in FY17.

Total BPD Reports by Manufacturing System
Licensed Non-Blood Establishments
FY17

Table 26

Manufacturing System	Allergenic	Blood Derivative	In-Vitro Diagnostic	Vaccine	351 HCT/P	TOTAL	
Product Specifications	67	70	88	71	8	304	52.8%
Quality Control & Distribution	2	10	26	41	0	79	13.7%
Labeling	2	16	11	17	12	58	10.1%
Process Controls	0	21	3	20	1	45	7.8%
Testing	2	13	5	24	1	45	7.8%
Miscellaneous	0	1	1	26	0	28	4.9%
Incoming Material	0	11	0	4	2	17	3.0%
Total	**73**	**142**	**134**	**203**	**24**	**576**	**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[6] [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 FY17. The summary does not provide individual product type specifics, but divides the reports only by being for cellular (e.g., hematopoietic stem/progenitor cells) or tissue (e.g., skin, musculoskeletal, cornea) products.

Manufacturers of 361 HCT/Ps submitted 38 fewer reports in FY17 than in the previous fiscal year (FY16-259) (Table 2). The number of reports submitted in FY17 by manufacturers of 361 HCT/Ps is displayed in Table 27.

- There were nine fewer reports involving **cellular HCT/Ps** submitted in FY17 as compared to in the previous fiscal year (FY16-134) (Table 6).
- In FY16, the distribution of a product with a positive culture result was captured under two deviation codes (SD-*Receipt, Pre-Distribution, Shipment, & Distribution* and PC-

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

Process Controls). In FY17, we captured these events under one deviation code (SD-*Receipt, Pre-Distribution, Shipment, & Distribution*).
    - There were 49 fewer reports involving processing and process controls submitted in FY17 as compared to in the previous fiscal year (FY16-75, FY17-26).
        - The number of reports involving contamination or potential contamination during processing decreased from 73 in FY16 to 17 in FY17.
    - There were 49 more reports involving receipt, pre-distribution, shipment and distribution submitted in FY17 as compared to in the previous fiscal year (FY16-37, FY17-86).
        - The number of reports involving distribution of product that was contaminated or potentially contaminated increased from 31 in FY16 to 84 in FY17.
- There were 29 fewer reports involving **tissue HCT/Ps** submitted in FY17 as compared to in the previous fiscal year (FY16-125) (Table 6).
- In FY16, the distribution of a product with a positive culture result was captured under three deviation codes (DE-*Donor Eligibility*, SD-*Receipt, Pre-Distribution, Shipment, & Distribution* and PC- *Process Controls*). In FY17, we captured these events under one deviation code (SD-*Receipt, Pre-Distribution, Shipment, & Distribution*)
    - The number of reports involving donor eligibility decreased from 53 in FY16 to 28 in FY17.
        - There were 24 fewer reports involving the acceptance of ineligible donors as compared to in the previous fiscal year (FY16-52, FY17-28). In FY17, 23 of these reports involved risk factors, clinical or physical evidence identified.
    - The number of reports involving receipt, pre-distribution, shipment and distribution increased from 22 in FY16 to 31 in FY17.
        - The number of reports involving distribution of product that was contaminated or potentially contaminated increased from two in FY16 to 19 in FY17.
        - The number of reports involving inappropriate shipping conditions decreased from 12 in FY16 to one in FY17.
    - The number of reports involving processing and processing controls decreased from 13 in FY16 to three in FY17.
    - The number of reports involving donor screening was similar to the number of reports submitted in the previous fiscal year (FY16-13, FY17-11).
        - The number of reports in which the donor medical history interview was not performed or performed incorrectly was similar to the number of reports submitted in the previous fiscal year (FY16-7, FY17-10).
        - The number of reports in which the donor medical record review was not performed or performed incorrectly was similar to the number of reports submitted in the previous fiscal year (FY16-5, FY17-1).
    - The number of reports involving donor testing was similar to the number of reports submitted in the previous fiscal year (16 in FY16 compared to 12 in FY17).

- The number of reports involving unacceptable samples used for testing was similar to the number of reports submitted in the previous fiscal year (FY16-13, FY17-12).
    - Three of these reports involved samples that did not meet requirements in the test kit package insert.
    - Nine of these reports involved samples collected from donors who were incorrectly evaluated or not evaluated for plasma dilution.
- There were no reports received in FY17 in which testing was not performed or performed incorrectly (FY16-3).

Total Reports by Manufacturing System
361 HCT/P Establishments
FY17

Table 27

HCT/P Deviation Code	Cellular HCT/P	Tissue HCT/P	Total	
Receipt, Pre-Distribution, Shipment & Distribution	86	31	117	52.9%
Processing and Processing Controls	26	3	29	13.1%
Donor Eligibility	1	28	29	13.1%
Donor Testing	3	12	15	6.8%
Supplies and Reagents	8	4	12	5.4%
Donor Screening	0	11	11	5.0%
Labeling Controls	0	3	3	1.4%
Recovery	0	3	3	1.4%
Environmental Control	1	0	1	0.5%
Storage	0	1	1	0.5%
Equipment	0	0	0	0.0%
Total	**125**	**96**	**221**	**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 Biological Product and HCT/P Deviation Reports - 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. 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 9/2017
https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM574889.pdf