Biological Product and HCT/P Deviation Reports

Annual Summary for Fiscal Year 2019

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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 an event associated with manufacturing (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].

In addition, 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)] are required to submit 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 to the prevention of communicable disease transmission or HCT/P contamination.

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 https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations. The guidance document for blood and Source Plasma establishments was updated in March 2020 and explained that we do not consider post donation information (PDI) events to require BPD reports. See https://www.fda.gov/media/70694/download. A guidance document for deviation reporting for 361 HCT/Ps (Ref. 3) is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deviation-reporting-human-cells-tissues-and-cellular-and-tissue-based-products-regulated-solely.

This annual summary report provides an overview of the reports we received during the fiscal year encompassing October 1, 2018, through September 30, 2019, including detailed information regarding the number and types of deviation reports received. Each firm responsible for reporting biological product and HCT/P deviations should use this information in evaluating their own deviation management program. We provide combined data received over the last three fiscal years to compare data and highlight changes. However, based on the limited data, we may not be able to determine the reason for changes to the number of reports submitted compared to the previous fiscal year.

Detailed information for blood and Source Plasma establishments can be found in Appendix 1; detailed information for licensed non-blood establishments can be found in Appendix 2; and

detailed information for 361 HCT/P establishments can be found in Appendix 3. Previous summary reports are available at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviation-reports-annual-summaries. 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. For example, in calendar year 2017, 10.6 million whole blood and red cells, 1.8 million apheresis platelets, and 2.4 million plasma components were transfused, with a continued but slowing decline in demand for RBCs compared to 2015.[1] In addition, there were 48.7 million Source Plasma donations in 2018.[2]

Table 1 shows the number of reports received and the number of establishments who submitted reports each fiscal year for the past three years for each type of establishment. Although CBER received more than 49,248 reports during fiscal year 2019 (hereafter FY19), this summary excludes data for BPD reports that did not meet the reporting requirements. We notified the reporter when a report was not required. There was a 4.9% increase in the number of reports we received in FY19 (2,281 reports) compared to FY18. The total number of reporting establishments increased from 2,104 in FY18 to 2,158 in FY19. Compared to FY18, there were 48 more blood and Source Plasma establishments, 4 fewer manufacturers of licensed biological products other than blood and blood components, and ten more 361 HCT/P manufacturers reporting in FY19.

[1] Jones et al. Slowing decline in blood collection and transfusion in the United States–2017.Transfusion 2020;60: S1-S6.

[2] Plasma Protein Therapeutics Association at https://www.pptaglobal.org/images/Data/Plasma_Collection/2009-2018_US_TC.pdf

Table 1 - Total Deviation Reports FY17 - FY19

Establishment Type	Number of Reporting Establishments			Total Reports Received			*Potential* Recalls		
	FY17	FY18	FY19	FY17	FY18	FY19	FY17	FY18	FY19
Blood/Source Plasma Manufacturers									
Licensed Blood Establishments	206 (87*)	215 (86*)	222(86*)	17,958	16,351	15,826	526	471	449
Unlicensed Blood Establishments[1]	381	377	359	3,312	3,509	3,159	14	8	14
Transfusion Services[2]	697	709	691	2,080	2,051	1,909	0	0	0
Source Plasma Establishments	567 (23*)	636(22*)	713(21*)	28,106	24,279	27,550	57	124	269
Sub-Total	*1,851*	*1,937*	*1,985*	*51,456*	*46,190*	*48,444*	*597*	*603*	*732*
Licensed Non-Blood Manufacturers									
Allergenic	7 (7*)	7 (7*)	6(6*)	73	64	88	1	3	0
Blood Derivative	23 (19*)	28 (23*)	24(19*)	142	137	119	3	3	5
In Vitro Diagnostic	10 (10*)	11 (11*)	9(8*)	134	105	93	3	3	1
Vaccine	17 (15*)	22 (19*)	17(15*)	203	194	193	1	0	1
351 HCT/P	4 (2*)	6(4*)	11(9*)	23	34	50	0	0	0
Gene Therapy Products	1(1*)	0	3(3*)	1	0	3	0	0	0
Sub-Total	*62 (54*)*	*74 (65*)*	*70(60*)*	*576*	*534*	*546*	*8*	*9*	*7*
361 HCT/P Manufacturers									
Cellular HCT/P	48	49	50	125	150	143	0	0	0
Tissue HCT/P	42	44	53	96	93	115	26	16	22
Sub-Total	*90*	*93*	*103*	*221*	*243*	*258*	*26*	*16*	*22*
Total	**2,003**	**2,104**	**2,158**	**52,253**	**46,967**	**49,248**	**631**	**628**	**761**

[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.

Table 2 shows the number of reports received each fiscal year for the past three years for blood and Source Plasma establishments. Blood and Source Plasma establishments submitted 98.4% of the total reports in FY19 and 2,254 more reports in FY19 compared to FY18. Licensed blood establishments submitted 33%, unlicensed registered blood establishments submitted 7%, transfusion services submitted 4%, and Source Plasma establishments submitted 57% of the total blood and Source Plasma reports in FY19. Compared to FY18, licensed blood establishments submitted 525 fewer reports, unlicensed registered blood establishments submitted 350 fewer reports, transfusion services 142 fewer reports, and Source Plasma establishments submitted 3,271 more reports in FY19, most likely due to an increase in new Source Plasma locations. To compare reports received in FY17 and FY18 with FY19, the data was adjusted to account for the changes in the BPD codes implemented in FY19, e.g., elimination of the miscellaneous blood and licensed non-blood codes.

Table 2 - Blood and Source Plasma Establishments

Licensed Blood Establishments

Manufacturing System	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Post Donation Information	12,793	71.2%	11,497	70.3%	11,358	71.8%
QC & Distribution	2,420	13.5%	1,886	11.5%	1,696	10.7%
Donor Screening	860	4.8%	864	5.3%	1,210	7.6%
Blood Collection	918	5.1%	1,209	7.4%	868	5.5%
Labeling	472	2.6%	403	2.5%	292	1.8%
Routine Testing	198	1.1%	229	1.4%	234	1.5%
Component Preparation	180	1.0%	164	1.0%	106	0.7%
Transfusion-Transmitted Infection Testing	92	0.5%	84	0.5%	49	0.3%
Donor Deferral	25	0.1%	15	0.1%	13	0.1%
Total	**17,958**	100%	**16,351**	100%	**15,826**	100%

Unlicensed Blood Establishments

Manufacturing System	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
QC & Distribution	1,633	49.3%	1,836	52.3%	1,747	55.3%
Labeling	843	25.5%	823	23.5%	625	19.8%
Routine Testing	428	12.9%	464	13.2%	442	14.0%
Post Donation Information	243	7.3%	220	6.3%	184	5.8%
Component Preparation	63	1.9%	88	2.5%	74	2.3%
Transfusion-Transmitted Infection Testing	42	1.3%	39	1.1%	54	1.7%
Donor Screening	36	1.1%	32	0.9%	24	0.8%
Blood Collection	22	0.7%	4	0.1%	8	0.3%
Donor Deferral	2	0.1%	3	0.1%	1	<0.0%
Total	**3,312**	100%	**3,509**	100%	**3,159**	100%

Transfusion Services

Manufacturing System	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
QC & Distribution	1,037	49.9%	1,060	51.7%	980	51.3%
Routine Testing	524	25.2%	540	26.3%	566	29.6%
Labeling	514	24.7%	447	21.8%	357	18.7%
Component Preparation	5	0.2%	3	0.1%	3	0.2%
Transfusion-Transmitted Infection Testing*	NA	NA	1	<0.0%	3	0.2%
Post Donation Information	NA	NA	NA	NA	NA	NA
Donor Screening	NA	NA	NA	NA	NA	NA
Blood Collection	NA	NA	NA	NA	NA	NA
Donor Deferral	NA	NA	NA	NA	NA	NA
Total	**2,080**	100%	**2,051**	100%	**1,909**	100%

**Bacterial detection testing*

Source Plasma Establishments

Manufacturing System	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Post Donation Information	24,235	86.2%	19,924	82.1%	23,544	85.5%
QC & Distribution	3,635	12.9%	3,920	16.1%	3,587	13.0%
Donor Screening	174	0.6%	311	1.3%	343	1.2%
Donor Deferral	16	0.1%	8	<0.0%	41	0.1%
Blood Collection	9	<0.0%	42	0.2%	29	0.1%
Labeling	4	<0.0%	6	<0.0%	4	<0.0%
Component Preparation	3	<0.0%	0	0.0%	1	<0.0%
Transfusion-Transmitted Infection Testing	30	0.1%	43	0.2%	1	<0.0%
Routine Testing	0	0.0%	25	0.1%	0	0.0%
Total	**28,106**	100%	**24,279**	100.	**27,550**	100%

Table 3 shows the number of reports received each fiscal year for the past three years for licensed biological products other than blood and blood components (licensed non-blood) manufacturers. Manufacturers of licensed non-blood products submitted 1.1% of the total reports in FY19 and 12 more reports in FY19 compared to FY18. Allergenic manufacturers submitted 16%, blood derivative manufacturers submitted 22%, in-vitro diagnostic manufacturers submitted 17%, vaccine manufacturers submitted 35%, licensed HCT/P manufacturers (351 HCT/Ps) submitted 9%, and gene therapy product manufacturers submitted 1% of the total licensed non-blood reports in FY19. Compared to FY18, allergenic manufacturers submitted 24 more reports, blood derivative manufacturers submitted 18 fewer reports, in-vitro diagnostic manufacturers submitted 12 fewer reports, vaccine manufacturers submitted one less report, licensed HCT/P manufacturers (351 HCT/Ps) submitted 16 more reports, and gene therapy product manufacturers submitted three more reports in FY19.

Table 3 - Licensed Non-Blood Manufacturers

Allergenic Manufacturers

Manufacturing System	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Product Specifications	67	91.8%	54	84.4%	85	96.6%
Labeling	2	2.7%	4	6.2%	2	2.3%
Process Controls	0	0%	1	1.6%	1	1.1%
Quality Control & Distribution	2	2.7%	4	6.2%	0	0%
Testing	2	2.7%	1	1.6%	0	0%
Incoming Material	0	0%	0	0%	0	0%
Total	**73**	100%	**64**	100%	**88**	100%

Blood Derivatives Manufacturers

Manufacturing System	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Product Specifications	70	49.3%	50	36.5%	54	45.4%
Quality Control & Distribution	11	7.7%	25	18.2%	22	18.5%
Testing	13	9.2%	7	5.1%	14	11.8%
Labeling	16	11.3%	23	16.8%	13	10.9%
Incoming Material	11	7.7%	14	10.2%	10	8.4%
Process Controls	21	14.8%	18	13.1%	6	5.0%
Total	**142**	100%	**137**	100%	**119**	100%

In-Vitro Diagnostic Manufacturers

Manufacturing System	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Product Specifications	89	66.4%	70	66.7%	49	52.7%
Quality Control & Distribution	26	19.4%	18	17.1%	24	25.8%
Labeling	11	8.2%	15	14.3%	15	16.1%
Testing	5	3.7%	0	0%	4	4.3%
Process Controls	3	2.2%	2	1.9%	1	1.1%
Incoming Material	0	0%	0	0%	0	0%
Total	**134**	100%	**105**	100%	**93**	100%

Vaccine Manufacturers

Manufacturing System	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Product Specifications	96	47.3%	92	47.4%	83	43.0%
Quality Control & Distribution	42	20.7%	44	22.7%	49	25.4%
Process Controls	20	9.9%	24	12.4%	24	12.4%
Testing	24	11.8%	23	11.9%	21	10.9%
Labeling	17	8.4%	7	3.6%	12	6.2%
Incoming Material	4	2.0%	4	2.1%	4	2.1%
Total	**203**	100%	**194**	100%	**193**	100%

351 HCT/P Manufacturers

Manufacturing System	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Product Specifications	7	30.4%	10	29.4%	20	40.0%
Labeling	12	52.2%	15	44.1%	18	36.0%
Quality Control & Distribution	0	0%	3	8.8%	4	8.0%
Process Controls	1	4.3%	1	2.9%	4	8.0%
Incoming Material	2	8.7%	2	5.9%	2	4.0%
Testing	1	4.3%	3	8.8%	1	2.0%
Receipt, Pre-Distribution Shipment, Distribution	0	0%	0	0%	1	2.0%
Total	**23**	100%	**34**	100%	**50**	100%

Gene Therapy Product Manufactures

Manufacturing System	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Product Specifications	1	100%	0	0%	2	66.7%
Testing	0	0%	0	0%	1	33.3%
Labeling	0	0%	0	0%	0	0%
Quality Control & Distribution	0	0%	0	0%	0	0%
Incoming Material	0	0%	0	0%	0	0%
Process Controls	0	0%	0	0%	0	0%
Total	**1**	100%	**0**	0%	**3**	100%

Table 4 shows the number of reports received each fiscal year for the past three years for 361 HCT/P manufacturers. Manufacturers of 361 HCT/Ps submitted 0.5% of the total reports in FY19 and 15 more reports in FY19 compared to FY18. Manufacturers of cellular 361 HCT/Ps (e.g., hematopoietic stem/progenitor cells) submitted 55% and manufacturers of tissue 361 HCT/Ps (e.g., skin, musculoskeletal, cornea) submitted 45% of the total 361 HCT/P deviation reports in FY19. Compared to FY18, manufacturers of cellular 361 HCT/Ps submitted seven fewer reports and manufacturers of tissue 361 HCT/Ps submitted 22 more reports in FY19.

Table 4 - 361 HCT/P Manufacturers

Cellular 361 HCT/P Manufacturers

Manufacturing System	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Receipt, Pre-Distribution, Shipment & Distribution	86	68.8%	118	78.7%	119	83.2%
Processing & Processing Controls	26	20.8%	15	10.0%	11	7.7%
Donor Screening	0	0.0%	12	8.0%	6	4.2%
Supplies and Reagents	8	6.4%	2	1.3%	3	2.1%
Donor Testing	3	2.4%	2	1.3%	2	1.4%
Donor Eligibility	1	0.8%	1	0.7%	1	0.7%
Environmental Control	1	0.8%	0	0.0%	1	0.7%
Equipment	0	0.0%	0	0.0%	0	0.0%
Storage	0	0.0%	0	0.0%	0	0.0%
Labeling Controls	0	0.0%	0	0.0%	0	0.0%
Recovery	0	0.0%	0	0.0%	0	0.0%
Total	**125**	100%	**150**	100%	**143**	100%

Tissue 361 HCT/Ps Manufacturers

Manufacturing System	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Recovery	3	3.1%	8	8.6%	31	27.0%
Receipt, Pre-Distribution, Shipment & Distribution	31	32.3%	22	23.7%	30	26.1%
Donor Eligibility	28	29.2%	33	35.5%	22	19.1%
Processing & Processing Controls	3	3.1%	6	6.5%	12	10.4%
Donor Screening	11	11.5%	6	6.5%	8	7.0%
Donor Testing	12	12.5%	11	11.8%	7	6.1%
Equipment	0	0.0%	3	3.2%	2	1.7%
Labeling Controls	3	3.1%	1	1.0%	2	1.7%
Supplies and Reagents	4	4.2%	1	1.0%	1	0.9%
Storage	1	1.0%	2	2.2%	0	0.0%
Environmental Control	0	0.0%	0	0.0%	0	0.0%
Total	**96**	100%	**93**	100%	**115**	100%

We modified some of the Blood BPD Codes to clarify reportable events, which contributed to the change in the number of reports submitted by blood and Source Plasma establishments. We modified events related to distributed products:

- In which routine testing was not performed or not documented, which were previously captured under Quality Control and Distribution. In FY19, these events were captured under Routine Testing.
- In which a donor subsequently tested confirmed positive for a relevant transfusion-transmitted disease and previous units were distributed, which were previously captured under Miscellaneous. In FY19, these events were captured under Quality Control and Distribution.
- In which bacterial detection testing was not performed or not documented which were previously captured under Quality Control and Distribution. In FY19, these events were captured under Transfusion-Transmitted Infection Testing.

In FY19, we moved the Miscellaneous events in the Non-Blood BPD Codes to Product Specifications. There were no changes to the HCT/P Deviation Codes.

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).

II. References

1. Guidance for Industry - Biological Product Deviation Reporting for Blood and Plasma Establishments March 2020 https://www.fda.gov/media/70694/download
2. Guidance for Industry - Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components 10/18/2006 https://www.fda.gov/media/76309/download
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 September 2017 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deviation-reporting-human-cells-tissues-and-cellular-and-tissue-based-products-regulated-solely

III. Appendices

1. BPD Reports Submitted by Blood and Source Plasma Establishments
2. BPD Reports Submitted by Licensed Non-Blood Manufacturers
3. HCT/P Reports Submitted 361 HCT/P Manufacturers

Appendix 1. BPD Reports Submitted by Blood and Source Plasma Establishments

Tables 5 through 17 highlight the most frequent reports submitted in FY19 by each type of blood and Source Plasma establishment compared to reports submitted in FY18. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports received listed in the table.

1. Most Frequent BPD Reports Submitted by Licensed Blood Establishments[3]

Of the 15,826 reports submitted by licensed blood establishments in FY19 (Table 2), 11,358 reports (71.8%) involved **post donation information** (Table 5). There were 139 fewer reports submitted in FY19 compared to FY18 involving post donation information.

Table 5 - Most Frequent BPD Reports - Post Donation Information from Licensed Blood Establishments

Post Donation Information (PD)	FY18 (#)	FY18 (% of PD)	FY19 (#)	FY19 (% of PD)
Total PD Reports Received	**11,497**	**-**	**11,358**	**-**
Behavior/History	***10,642***	***92.6%***	***10,483***	***92.3%***
Travel to or residence in a malaria endemic area/history of malaria	3,926	34.1%	3,805	33.5%
Risk factors associated with Creutzfeldt-Jakob Disease (CJD) – travel	2,042	17.8%	2,217	19.5%
Donor received tattoo and/or piercing	1,420	12.4%	1,320	11.6%
Received finasteride, etretinate, isotretinoin, dutasteride	735	6.4%	749	6.6%
IV drug use not prescribed by a doctor	318	2.8%	328	2.9%
Male donor had sex with another man	297	2.6%	308	2.7%
Illness	***829***	***7.2%***	***837***	***7.4%***
Post donation illness (not hepatitis, HIV, HTLV-I, STD, cancer or cold/flu related)	756	6.6%	757	6.7%
Fever/diarrhea	449	3.9%	474	4.2%
Infection	184	1.6%	182	1.6%
Not specifically related to high risk behavior, unsuitable history, or post donation illness	***26***	***0.2%***	***38***	***0.3%***

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

Of the 15,826 reports submitted by licensed blood establishments in FY19 (Table 2), 1,696 reports (10.7%) involved **quality control and distribution** deviations or unexpected events (Table 6). The number of these reports increased 10% compared to FY18, which is an increase of 190 reports. There were 309 fewer reports submitted in FY19 compared to FY18 involving distributed units collected from a donor who subsequently tested confirmed positive for a relevant transfusion-transmitted infection, specifically related to Babesia and ZIKV. There were 204 more reports submitted in FY19 compared to FY18 involving bacterial detection testing.

Table 6 - Most Frequent BPD Reports - Quality Control & Distribution from Licensed Blood Establishments

QC & Distribution (QC)	FY18 (#)	FY18 (% of QC)	FY19 (#)	FY19 (% of QC)
Total QC Reports Received	**1,882**	**-**	**1,696**	**-**
Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease	***1,011***	***53.7%***	***702***	***41.4%***
HCV	310	16.5%	214	12.6%
HBV	148	7.9%	147	8.7%
Anti-HBc positive	64	3.4%	55	3.2%
HIV	96	5.1%	88	5.2%
West Nile Virus	104	5.5%	79	4.7%
Babesia	208	11.1%	72	4.2%
Zika Virus	119	6.3%	39	2.3%
Distribution of product that did not meet specifications	***453***	***24.1%***	***426***	***25.1%***
Product QC unacceptable, not performed, not documented, or incomplete	280	14.9%	221	13.0%
White Blood Cell count	90	4.8%	105	6.2%
Platelet count	52	2.8%	36	2.1%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or documented	39	2.1%	55	3.2%
Product in which specification other than QC was not met	36	1.9%	32	1.9%
Outdated product	18	1.0%	30	1.8%
Positive testing	***124***	***6.6%***	***310***	***18.3%***
Bacterial detection testing	103	5.5%	307	18.1%
Shipping and storage	***165***	***8.8%***	***117***	***6.9%***
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***101***	***5.4%***	***116***	***6.8%***
Distribution of unit collected from a donor implicated in a relevant transfusion-transmitted disease	***17***	***1.7%***	***13***	***0.8%***
Babesia	13	0.7%	11	0.6%

Of the 15,826 reports submitted by licensed blood establishments in FY19 (Table 2), 1,210 reports (7.6%) involved **donor screening** deviations or unexpected events (Table 7). The number of these reports increased 40% compared to FY18, which is an increase of 346 reports. involving donor screening. There were 409 more reports submitted in FY19 compared to FY18 involving deferral screening not performed or performed incorrectly prior to product distribution, but the donor was not previously deferred.

Table 7 - Most Frequent BPD Reports - Donor Screening from Licensed Blood Establishments

Donor Screening (DS)	FY18 (#)	FY18 (% of DS)	FY19 (#)	FY19 (% of DS)
Total DS Reports Received	**864**	**-**	**1,210**	**-**
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***491***	***56.8%***	***969***	***80.1%***
Donor not previously deferred	374	43.3%	783	64.7%
Donor previously deferred due to history	71	8.2%	115	9.5%
Donor previously deferred due to testing	46	5.3%	71	5.9%
Donor record incomplete or incorrect	***221***	***25.6%***	***131***	***10.8%***
Donor history questions	204	23.6%	125	10.3%
Incorrect gender specific question asked or incorrect answer	178	20.6%	109	9.0%
Donor gave history which warranted deferral or follow up and was not deferred	***124***	***14.4%***	4	0.3%
Travel to malaria endemic area/history of malaria	72	8.3%	***96***	***7.9%***
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel	32	3.7%	55	4.5%
Donor did not meet acceptance criteria	***26***	***3.0%***	19	1.6%

Of the 15,826 reports submitted by licensed blood establishments in FY19 (Table 2), 868 reports (5.5%) involved **blood collection** deviations or unexpected events (Table 8)**.** The number of these reports decreased 28% compared to FY18, which is a decrease of 341 reports. The number of reports involving clots or fibrin discovered in a product decreased 30%.

Table 8 - Most Frequent BPD Reports – Blood Collection From Licensed Blood Establishments

Blood Collection (BC)	FY18 (#)	FY18 (% of BC)	FY19 (#)	FY19 (% of BC)
Total BC Reports Received	**1,209**	**-**	**868**	**-**
Collection process	***1,090***	***90.2%***	***776***	***89.4%***
Product contained clots or fibrin, not discovered prior to distribution	1,058	87.5%	739	85.1%
Product hemolyzed, not discovered prior to distribution	19	1.6%	20	2.3%
Sterility compromised	***104***	***8.6%***	***74***	***8.5%***
Bacterial contamination	83	6.9%	67	7.7%
Arm prep not performed or performed inappropriately	16	1.3%	5	0.6%

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

Of the 3,159 reports submitted by unlicensed registered blood establishments in FY19 (Table 2), 1,747 reports (55.3%) involved **quality control and distribution** deviations or unexpected events (Table 9)**.** The number of these reports decreased 5% compared to FY18, which is a decrease of 89 reports.

Table 9 - Most Frequent BPD Reports - Quality Control & Distribution from Unlicensed Registered Blood Establishments

QC & Distribution (QC)	FY18 (#)	FY18 (% of QC)	FY19 (#)	FY19 (% of QC)
Total QC Reports Received	**1,836**	**-**	**1,747**	**-**
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***1,616***	***88.0%***	***1,533***	***87.8%***
Visual inspection not performed, not documented, or inadequate, includes product not documented or incorrectly documented as issued in the computer	769	41.9%	653	37.4%
Product not irradiated as required	193	10.5%	212	12.1%
Improper product selected for patient	212	11.5%	192	11.0%
Improper ABO or Rh type selected for patient	132	7.2%	133	7.6%
Procedure for issuing not performed or documented in accordance with specifications	108	5.9%	114	6.5%
Product issued to wrong patient	58	3.2%	65	3.7%
Distribution of product that did not meet specifications	***141***	***7.7%***	***157***	***9.0%***
Product in which instrument QC, calibration, or validation unacceptable, incomplete or not documented	25	1.4%	56	3.2%
Product in which specification, other than QC, was not met	42	2.3%	33	1.9%
Outdated product	33	1.8%	30	1.7%
Product QC unacceptable, not performed, not documented or incomplete	31	1.7%	18	1.0%

Of the 3,159 reports submitted by unlicensed registered blood establishments in FY19 (Table 2), 625 reports (19.8%) involved **labeling** deviations or unexpected events (Table 10). The number of these reports decreased 24% compared to FY18, which is a decrease of 198 reports.

Table 10 - Most Frequent BPD Reports – Labeling from Unlicensed Registered Blood Establishments

Labeling (LA)	FY18 (#)	FY18 (% of LA)	FY19 (#)	FY19 (% of LA)
Total LA Reports Received	**823**	**-**	**625**	**-**
Crossmatch tag, tie tag, to transfusion record incorrect or missing information	***556***	***67.6%***	***389***	***62.2%***
Recipient identification incorrect or missing	141	17.1%	163	26.1%
Crossmatch tag, tie tag, or transfusion record incorrect or missing or attached to incorrect unit	68	8.3%	60	9.6%
Expiration date or time extended or missing	38	4.6%	49	7.8%
Unit, lot, or pool number incorrect or missing	21	2.6%	27	4.3%
Product type or code incorrect or missing	35	4.3%	18	2.9%
Labels applied to blood unit or product incorrect or missing information	***267***	***32.4%***	***236***	***37.8%***
Extended or missing expiration date or time	114	13.9%	109	17.4%
Irradiation status incorrect or missing	45	5.5%	38	6.1%
Product type or code incorrect or missing	33	4.0%	28	4.5%
Product volume or weight incorrect or missing	31	3.8%	20	3.2%
Combination of incorrect or missing information	16	1.9%	15	2.4%
Donor/unit number or lot number incorrect or missing	10	1.2%	7	1.1%

Of the 3,159 reports submitted by unlicensed registered blood establishments in FY19 (Table 2), 442 reports (14.0%) involved **routine testing** deviations or unexpected events (Table 11). The number of these reports decreased 5% compared to FY18, which was a decrease of 22 reports.

Table 11 - Most Frequent BPD Reports - Routine Testing from Unlicensed Registered Blood Establishments

Routine Testing (RT)	FY18 (#)	FY18 (% of RT)	FY19 (#)	FY19 (% of RT)
Total RT Reports Received	**464**	**-**	**442**	**-**
Testing performed, interpreted, or documented incorrectly	***408***	***87.9%***	***376***	***85.1%***
Compatibility	96	20.7%	106	24.0%
Antibody screening or identification	106	22.8%	87	19.7%
ABO and/or Rh	97	20.9%	80	18.1%
Antigen typing	81	17.5%	71	16.1%
Sample (used for testing) identification	***54***	***11.6%***	***66***	***14.9%***
Sample used for testing was incorrectly or incompletely labeled	29	6.3%	35	7.9%
Unsuitable sample used for testing (e.g., too old)	13	2.8%	18	4.1%
Incorrect sample tested	12	2.6%	12	2.7%

3. Most Frequent BPD Reports Submitted by Transfusion Services

Of the 1,909 reports submitted by transfusion services in FY19 (Table 2), 980 reports (51.3%) involved **quality control and distribution** deviations or unexpected events (Table 12). The number of these reports decreased 8% compared to FY18, which was a decrease of 80 reports.

Table 12 - Most Frequent BPD Reports - Quality Control & Distribution from Transfusion Services

QC & Distribution (QC)	FY18 (#)	FY18 (% of QC)	FY19 (#)	FY19 (% of QC)
Total QC Reports Received	**1,060**	**-**	**980**	**-**
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***940***	***88.7%***	***934***	***95.3%***
Visual inspection not performed, not documented, or inadequate, includes product not documented or incorrectly documented as issued in the computer	405	38.2%	396	40.4%
Product not irradiated as required	127	12.0%	127	13.0%
Improper product selected for patient	95	9.0%	105	10.7%
Procedure for issuing not performed or documented in accordance with specifications	105	9.9%	95	9.7%
Improper ABO or Rh type selected for patient	70	6.6%	70	7.1%
Distribution of product that did not meet specifications	***62***	***5.8%***	***62***	***6.3%***
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or not documented	20	1.9%	26	2.7%
Outdated product	26	2.5%	20	2.0%
Product in which specification other than QC not met	10	0.9%	10	1.0%
Shipping and storage	***46***	***4.3%***	***46***	***4.7%***
Temperature not recorded or unacceptable upon return, unit redistributed	11	1.0%	19	1.9%
Product stored at incorrect temperature	19	1.8%	11	1.1%
No documentation that product was shipped or stored at appropriate temperature	9	0.8%	9	0.9%

Of the 1,909 reports submitted by transfusion services in FY19 (Table 2), 566 reports (29.6%) involved **routine testing** deviations or unexpected events (Table 13). The number of these reports increased 5% compared to FY18, which was an increase of 26 reports.

Table 13 - Most Frequent BPD Reports - Routine Testing from Transfusion Services

Routine Testing (RT)	FY18 (#)	FY18 (% of RT)	FY19 (#)	FY19 (% of RT)
Total RT Reports Received	**540**	**-**	**566**	**-**
Testing performed, interpreted, or documented incorrectly	***476***	***88.1%***	***502***	***88.7%***
Antigen typing	108	20.0%	124	21.9%
Antibody screening or identification	108	20.0%	119	21.0%
Compatibility	130	24.1%	118	20.8%
ABO and/or Rh typing	93	17.2%	88	15.5%
Sample (used for testing) identification	***64***	***11.9%***	***64***	***11.3%***
Sample used for testing was incorrectly or incompletely labeled	44	8.1%	49	8.7%
Incorrect sample tested	11	2.0%	8	1.4%
Unsuitable sample used for testing	9	1.7%	6	1.1%

Of the 1,909 reports submitted by transfusion services in FY19 (Table 2), 357 reports (18.7%) involved **labeling** deviations or unexpected events (Table 14). The number of these reports decreased 20% compared to FY18, which was a decrease of 90 reports.

Table 14 - Most Frequent BPD Reports - Labeling from Transfusion Services

Labeling (LA)	FY18 (#)	FY18 (% of LA)	FY19 (#)	FY18 (% of LA)
Total LA Reports Received	**447**	**-**	**357**	**-**
Crossmatch tag, tie tag or transfusion record incorrect or missing information	***388***	***86.8%***	***282***	***79.0%***
Recipient identification incorrect or missing	107	23.9%	137	38.4%
Crossmatch tag or tie tag missing or attached to incorrect unit	47	10.5%	42	11.8%
Product type or code incorrect or missing	31	6.9%	18	5.0%
Expiration date or time extended or missing	19	4.3%	17	4.8%
Antigen incorrect or missing	4	0.9%	13	3.6%
Combination of incorrect or missing information	8	1.8%	10	2.8%
Labels applied to blood unit or product incorrect or missing information	***59***	***13.2%***	***75***	***21.0%***
Extended or missing expiration date or time	18	4.0%	36	10.1%
Combination of incorrect or missing information	6	1.3%	12	3.4%
Product volume or weight incorrect or missing	3	0.7%	7	2.0%

4. Most Frequent BPD Reports Submitted by Source Plasma Establishments

Of the 27,550 reports submitted by Source Plasma establishments in FY19 (Table 2), 23,544 reports (85.5%) involved **post donation information** (Table 15)**.** The number of these reports increased 18% compared to FY18, which was an increase of 3,620 reports.

Table 15 - Most Frequent BPD Reports - Post Donation Information from Source Plasma Establishments

Post Donation Information (PD)	FY18 (#)	FY18 (% of PD)	FY19 (#)	FY19 (% of PD)
Total PD Reports Received	**19,924**	**-**	**23,544**	**-**
Behavior/History	***19,840***	***99.6%***	***23,460***	***99.6%***
Donor received tattoo and/or piercing	12,838	64.4%	14,980	63.6%
Donor deferred by another center due to history or tested reactive, specific history or testing unknown	2,821	14.2%	3,764	16.0%
Incarcerated	864	4.3%	959	4.1%
IV drug use not prescribed by a doctor	599	3.0%	758	3.2%
Intimate contact with risk for a relevant transfusion-transmitted infection - HCV	749	3.8%	754	3.2%
Other (unacceptable address; donor comprehension questionable)	631	3.2%	726	3.1%
Male donor had sex with another man	304	1.5%	312	1.3%
Illness	***71***	***0.4%***	***64***	***0.3%***
Post donation diagnosis or symptoms of Hepatitis C, or reactive test for Hepatitis C	32	0.2%	22	0.1%
Post donation diagnosis or symptoms of HIV, or reactive test for HIV	17	0.1%	22	0.1%
Post donation diagnosis or symptoms of Hepatitis B, or reactive test for Hepatitis B	9	0.0%	9	0.0%

Of the 27,550 reports submitted by Source Plasma establishments in FY19 (Table 2), 3,587 reports (13.0%) involved **quality control and distribution** deviations or unexpected events (Table 16)**.** The number of these reports decreased 8% compared to FY18, which was a decrease of 333 reports. Many reports of units collected from a donor who subsequently tested positive for atypical antibodies were submitted in FY18. In FY19, we determined this event was not reportable.

Table 16 - Most Frequent BPD Reports - Quality Control & Distribution from Source Plasma Establishments

QC & Distribution (QC)	FY18 (#)	FY18 (% of QC)	FY19 (#)	FY19 (% of QC)
Total QC Reports Received	**3,920**	**-**	**3,587**	**-**
Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease	***3,343***	***85.3%***	***3,490***	***97.3%***
HCV	1,892	48.3%	1,809	50.4%
HBV	979	25.0%	1,150	32.1%
HIV	462	11.8%	521	14.5%
Distribution of product that did not meet specifications	***96***	***2.4%***	***37***	1.0%
Product identified as unsuitable due to a donor screening deviation or unexpected event	8	0.2%	23	0.6%
Product identified as unsuitable due to a collection deviation or unexpected event	17	0.4%	8	0.2%
Positive testing for	***431***	***11.0%***	***33***	***0.9%***
HIV	0	0.0%	30	0.8%
Failure to quarantine unit due to medical history	***50***	***1.3%***	***26***	***0.7%***
Donor received tattoo and/or piercing	7	0.2%	12	0.3%
Post Donation Illness	33	0.8%	6	0.2%

Of the 27,550 reports submitted by Source Plasma establishments in FY18 (Table 2), 343 reports (1.2%) involved **donor screening** deviations or unexpected events (Table 17). The number of these reports increased 10% compared to FY18, which was an increase of 32 reports.

Table 17 - Most Frequent BPD Reports - Donor Screening from Source Plasma Establishments

Donor Screening (DS)	FY18 (#)	FY18 (% of DS)	FY19 (#)	FY19 (% of DS)
Total DS Reports Received	**311**	**-**	**343**	**-**
Donor record incomplete or incorrect	***167***	***53.7%***	***203***	***59.2%***
Donor history questions	121	38.9%	171	49.9%
Donor identification	45	14.5%	32	9.3%
Donor did not meet eligibility criteria	***12***	***3.9%***	***60***	***17.5%***
Medical review or physical examination not performed or inadequate	8	2.6%	59	17.2%
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***120***	***38.6%***	***54***	***15.7%***
Donor not previously deferred	73	23.5%	51	14.9%
Donor previously deferred due to history	47	15.1%	3	0.9%
Donor gave history which warranted deferral or follow up and was not deferred	***12***	***3.9%***	***26***	***7.6%***

Appendix 2. BPD Reports Submitted by Licensed Manufacturers of Biological Products Other Than Blood and Blood Components (Licensed Non-Blood)

Tables 18 through 23 highlight the most frequent reports submitted in FY19 by each type of licensed non-blood manufacturer compared to reports submitted in FY18. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports received listed in the table.

Of the 88 reports submitted by allergenic manufacturers in FY19 (Table 3), 97% of the reports were related to product specifications (Table 18).

Table 18 - Most Frequent BPD Reports Submitted by Allergenic Manufacturers

Allergenic Manufacturers	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Total Reports Received	**64**	-	**88**	-
Product Specifications	***54***	***84.4%***	***85***	***96.6%***
Product specification not met; contains precipitate	51	79.7%	80	90.9%

Of the 119 reports submitted by blood derivative manufacturers in FY19 (Table 3), 45% of the reports were related to product specifications and 19% of the reports were related to quality control and distribution (Table 19).

Table 19 - Most Frequent BPD Reports Submitted by Blood Derivative Manufacturers

Blood Derivative Manufacturers	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Total Reports Received	**137**	-	**119**	-
Product Specifications	***50***	***36.5%***	***54***	***45.4%***
Stability testing failed	30	21.9%	20	16.8%
Potency	21	15.3%	9	7.6%
Component packaged with final product did not meet specifications	9	6.6%	17	14.3%
Broken/cracked vial	7	5.1%	12	10.1%
Quality Control and Distribution	***25***	***18.2%***	***22***	***18.5%***
Packing; Broken or cracked vial/syringe	19	13.9%	14	11.8%

Of the 93 reports submitted by in-vitro diagnostic manufacturers in FY19 (Table 3), 53% of the reports were related to product specifications and 26% of the reports were related to quality control and distribution (Table 20).

Table 20 - Most Frequent BPD Reports Submitted by In-Vitro Diagnostic Manufacturers

In-Vitro Diagnostic Manufacturers	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Total Reports	**105**	-	**93**	-
Product Specifications	***70***	***66.7%***	***49***	***52.7%***
Product specification not met; Unexpected positive, negative, or weak reactions in testing	41	39.0%	29	31.2%
Quality Control and Distribution	***18***	***17.1%***	***24***	***25.8%***
Packing	16	15.2%	18	19.4%

Of the 193 reports submitted by vaccine manufacturers in FY19 (Table 3), 43% of the reports were related to product specifications and 25% of the reports were related to quality control and distribution (Table 21).

Table 21 - Most Frequent BPD Reports Submitted by Vaccine Manufacturers

Vaccine Manufacturers	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Total Reports	**194**	-	**193**	-
Product Specifications	***92***	***47.4%***	***83***	***43.0%***
Product specification not met	73	37.6%	71	36.8%
Appearance	32	16.5%	33	17.1%
Container closure not secure or damaged	29	14.9%	27	14.0%
Quality Control and Distribution	***44***	***22.7%***	***49***	***25.4%***
Packing	42	21.6%	49	25.4%

Of the 50 reports submitted by licensed HCT/P manufacturers in FY19 (Table 3), 40% of the reports were related to product specifications and 26% of the reports were related to labeling (Table 22).

Table 22 - Most Frequent BPD Reports Submitted by Licensed HCT/P Manufacturers

Licensed HCT/P Manufacturers	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Total Reports	**34**	-	**50**	-
Product Specifications	***10***	***29.4%***	***20***	***40.0%***
Product specification not met; contaminated with microorganism	7	20.6%	19	38.0%
Labeling	***15***	***44.1%***	***18***	***26.0%***
Product label; incorrect/illegible; recipient identification	13	38.2%	12	24.0%

Of the three reports submitted by gene therapy manufacturers in FY19 (Table 3), two reports were related to product specifications and one report was related to testing (Table 23).

Table 23 - Most Frequent BPD Reports Submitted by Gene Therapy Manufacturers

Licensed Gene Therapy Manufacturers	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Total Reports	**0**	-	**3**	-
Product Specifications	***0***	***0%***	***2***	***66.7%***
Testing	***0***	***0%***	***1***	***33.3%***

Appendix 3. HCT/P Deviation Reports Submitted by Manufacturers of 361 HCT/Ps

Tables 24 and 25 highlight the most frequent reports submitted in FY19 by each type of 361 HCT/P manufacturer compared to reports submitted in FY18. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports received listed in the table.

Of the 143 reports submitted by cellular 361 HCT/P manufacturers in FY19 (Table 4), 83% of the reports involved receipt, pre-distribution, shipment and distribution and 8% of the reports involved processing and process controls (Table 24).

Table 24 - Most Frequent HCT/P Deviation Reports Submitted by Cellular 361 HCT/Ps Manufacturers

Cellular 361 HCT/Ps Manufacturers	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Total Reports	**150**	-	**143**	-
Receipt, Pre-Distribution, Shipment & Distribution	***118***	***78.7%***	***119***	***83.2%***
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	117	78.0%	117	81.8%
Processing & Processing Controls	***15***	***10.0%***	***11***	***7.7%***
Processing; HCT/P contaminated, potentially contaminated, or cross-contaminated during processing	12	8.0%	6	4.2%

Of the 115 reports submitted by tissue 361 HCT/P manufacturers in FY19 (Table 4), 27% of the reports involved recovery, 26% involved receipt, pre-distribution, shipment and distribution and 19% of the reports involved donor eligibility and (Table 25). The increase in the number of reports involving recovery was due to eye tissue recovered using an eyewash that was recalled due to potential contamination.

Table 25 - Most Frequent HCT/P Deviation Reports Submitted by Tissue 361 HCT/Ps Manufacturers

Tissue 361 HCT/Ps Manufacturers	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)
Total Reports	**93**		**115**	
Recovery	***8***	***8.6%***	***31***	***27.0%***
Manner of recovery; HCT/P contaminated, potentially contaminated, or cross-contaminated during recovery	8	8.6%	31	27.0%
Receipt, Pre-Distribution, Shipment & Distribution	***22***	***23.7%***	***30***	***26.1%***
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	15	16.1%	21	18.3%
Donor Eligibility	***33***	***35.5%***	***22***	***19.1%***
Ineligible donor accepted; Risk factors for, or clinical evidence of infection due to RCDAD	29	31.2%	19	16.5%
Final autopsy results received post distribution	16	17.2%	5	4.3%