Biological Product and HCT/P Deviation Reports

Annual Summary for Fiscal Year 2020

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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. Hereafter, to improve the readability of this annual summary report, these products are collectively referred to as "361 HCT/Ps" rather than "nonreproductive HCT/Ps".

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-deviation-guidances-rules. The guidance document for blood and Source Plasma establishments was updated in March 2020 and explains that we do not consider post donation information (PDI) events to require BPD reports. PDI events historically represented approximately 70% of blood and Source Plasma reports submitted. As a result, there was a 53% decrease in the number of PDI events in FY20 (see Appendix 1 for details). 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 submitted during the fiscal year encompassing October 1, 2019, through September 30, 2020, including detailed information regarding the number and types of deviation reports. 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 submitted 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. These appendices provide data to compare fiscal year 2020 (FY20) to fiscal year 2019 (FY19), whereas Tables 1 through 4 below also include comparative data for fiscal year 2018 (FY18). 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, 12.2 million whole blood and apheresis Red Blood Cell (RBC) units were collected and 10.6 million whole blood-derived and apheresis RBC units, 1.9 million whole blood-derived and apheresis platelet units, 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 53.5 million Source Plasma donations in 2019.[2]

Table 1 shows the number of reports submitted and the number of establishments who submitted reports each fiscal year for the past three years for each type of establishment. Although there were more than 30,929 reports submitted during FY20, this summary excludes data for BPD reports that did not meet the reporting requirements. We notified the reporter when a report was not required.

The total number of reports submitted in FY20 (30,929) decreased 37.2% compared to FY19 (49,248). The total number of reporting establishments decreased from 2,159 in FY19 to 2,133 in FY20. Compared to FY19, there were five fewer blood and Source Plasma establishments, four more manufacturers of licensed biological products other than blood and blood components, and 24 fewer 361 HCT/P manufacturers reporting in FY20.

[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/Total_Yearly_Collections_2008-2019.pdf

Table 1 - Total Deviation Reports FY18 – FY20

Establishment Type	Number of Reporting Establishments			Total Reports Submitted			*Potential* Recalls		
	FY18	**FY19**	**FY20**	**FY18**	**FY19**	**FY20**	**FY18**	**FY19**	**FY20**
Blood/Source Plasma Manufacturers[1]									
Licensed Blood Establishments	215(86*)	222(86*)	200(78*)	16,351	15,826	9,769	471	449	396
Unlicensed Blood Establishments[2]	377	359	348	3,509	3,159	2,890	8	14	6
Transfusion Services[3]	709	691	671	2,051	1,909	1,785	0	0	0
Source Plasma Establishments	636(22*)	713(21*)	761(23*)	24,279	27,550	15,678	124	269	120
Sub-Total	*1,937*	*1,985*	*1,980*	*46,190*	*48,444*	*30,122*	*603*	*732*	*522*
Licensed Non-Blood Manufacturers									
Allergenic	7 (7*)	6 (6*)	8 (8*)	64	88	100	3	0	1
Blood Derivative	28 (23*)	24 (19*)	28 (23*)	137	119	117	3	5	1
In Vitro Diagnostic	11 (11*)	9 (8*)	10 (10*)	105	93	110	3	1	2
Vaccine	23 (20*)	18 (15*)	19 (17*)	194	193	255	0	1	0
351 HCT/P	6 (4*)	11 (9*)	8 (6*)	34	50	32	0	0	0
Gene Therapy Products	0	3 (3*)	1 (1*)	0	3	1	0	0	0
Sub-Total	*75 (65*)*	*71 (60*)*	*74 (65*)*	*534*	*546*	*615*	*9*	*7*	*4*
361 HCT/P Manufacturers									
Cellular HCT/P	49	50	47	150	143	130	0	0	0
Tissue HCT/P	44	53	32	93	115	62	16	22	16
Sub-Total	*93*	*103*	*79*	*243*	*258*	*192*	*16*	*22*	*16*
Total	**2,105**	**2,159**	**2,133**	**46,967**	**49,248**	**30,929**	**628**	**761**	**541**

[1] The data under "Total Reports Submitted" for FY20 represents a decrease in reporting due to the implementation of the BPD guidance (Ref. 1) eliminating reporting of post donation information.

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

[3]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 submitted each fiscal year for the past three years for blood and Source Plasma establishments. Blood and Source Plasma establishments submitted 97.4% of the total reports in FY20 and 18,322 fewer reports in FY20 compared to FY19. Licensed blood establishments submitted 32%, unlicensed registered blood establishments submitted 10%, transfusion services submitted 6%, and Source Plasma establishments submitted 52% of the total blood and Source Plasma reports in FY20. Compared to FY19, licensed blood establishments submitted 6,057 fewer reports (38% decrease), unlicensed registered blood establishments submitted 269 fewer reports (9% decrease), transfusion services submitted 124 fewer reports (6% decrease), and Source Plasma establishments submitted 11,872 fewer reports (43% decrease) in FY20.

Table 2 - Blood and Source Plasma Establishments

Licensed Blood Establishments

Manufacturing System	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Post Donation Information[1]	11,497	70.3%	11,358	71.8%	4,411	45.2%
QC & Distribution	1,886	11.5%	1,696	10.7%	1,823	18.7%
Donor Screening	864	5.3%	1,210	7.6%	1,586	16.2%
Blood Collection	1,209	7.4%	868	5.5%	1,118	11.4%
Labeling	403	2.5%	292	1.8%	290	3.0%
Routine Testing	229	1.4%	234	1.5%	263	2.7%
Component Preparation	164	1.0%	106	0.7%	217	2.2%
Transfusion-Transmitted Infection Testing	84	0.5%	49	0.3%	44	0.5%
Donor Deferral	15	0.1%	13	0.1%	17	0.2%
Total	**16,351**	100%	**15,826**	100%	**9,769**	100%

[1] The data under "Post Donation Information" for FY20 represents a decrease in reporting due to the implementation of the BPD guidance (Ref. 1) eliminating reporting of post donation information.

Unlicensed Blood Establishments

Manufacturing System	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
QC & Distribution	1,836	52.3%	1,747	55.3%	1,663	57.5%
Labeling	823	23.5%	625	19.8%	542	18.8%
Routine Testing	464	13.2%	442	14.0%	460	15.9%
Post Donation Information[1]	220	6.3%	184	5.8%	110	3.8%
Component Preparation	88	2.5%	74	2.3%	61	2.1%
Transfusion-Transmitted Infection Testing	39	1.1%	54	1.7%	30	1.0%
Donor Screening	32	0.9%	24	0.8%	21	0.7%
Blood Collection	4	0.1%	8	0.3%	3	0.1%
Donor Deferral	3	0.1%	1	<0.0%	0	0.0%
Total	**3,509**	100%	**3,159**	100%	**2,890**	100%

[1] The data under "Post Donation Information" for FY20 represents a decrease in reporting due to the implementation of the BPD guidance (Ref. 1) eliminating reporting of post donation information.

Transfusion Services

Manufacturing System	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
QC & Distribution	1,060	51.7%	980	51.3%	1,002	56.1%
Routine Testing	540	26.3%	566	29.6%	472	26.5%
Labeling	447	21.8%	357	18.7%	305	17.1%
Component Preparation	3	0.1%	3	0.2%	5	0.3%
Transfusion-Transmitted Infection Testing*	1	<0.0%	3	0.2%	1	0.1%
Donor Screening	NA	NA	NA	NA	NA	NA
Blood Collection	NA	NA	NA	NA	NA	NA
Donor Deferral	NA	NA	NA	NA	NA	NA
Post Donation Information	NA	NA	NA	NA	NA	NA
Total	**2,051**	100%	**1,909**	100%	**1,785**	100%

**Bacterial detection testing*

Source Plasma Establishments

Manufacturing System	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Post Donation Information[1]	19,924	82.1%	23,544	85.5%	11,904	75.9%
QC & Distribution	3,920	16.1%	3,587	13.0%	3,173	20.2%
Donor Screening	311	1.3%	343	1.2%	540	3.4%
Blood Collection	42	0.2%	29	0.1%	45	0.3%
Donor Deferral	8	<0.0%	41	0.1%	8	0.1%
Labeling	6	<0.0%	4	<0.0%	3	<0.0%
Component Preparation	0	0.0%	1	<0.0%	3	<0.0%
Transfusion-Transmitted Infection Testing	43	0.2%	1	<0.0%	2	<0.0%
Routine Testing	25	0.1%	0	0.0%	0	0.0%
Total	**24,279**	100%	**27,550**	100%	**15,678**	100%

[1] The data under "Post Donation Information" for FY20 represents a decrease in reporting due to the implementation of the BPD guidance (Ref. 1) eliminating reporting of post donation information.

Table 3 shows the number of reports submitted 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 2.0% of the total reports in FY20 and 69 more reports in FY20 compared to FY19. Allergenic manufacturers submitted 16%, blood derivative manufacturers submitted 19%, in-vitro diagnostic manufacturers submitted 18%, vaccine manufacturers submitted 42%, licensed HCT/P manufacturers (351 HCT/Ps) submitted 5%, and gene therapy product manufacturers submitted less than 1% of the total licensed non-blood reports in FY20. Compared to FY19, allergenic manufacturers submitted 12 more reports, blood derivative manufacturers submitted two fewer reports, in-vitro diagnostic manufacturers submitted 17 more reports, vaccine manufacturers submitted 62 more reports, licensed HCT/P manufacturers submitted 18 fewer reports, and gene therapy product manufacturers submitted two fewer reports in FY20.

Table 3 - Licensed Non-Blood Manufacturers

Allergenic Manufacturers

Manufacturing System	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Product Specifications	54	84.4%	85	96.6%	93	93.0%
Labeling	4	6.2%	2	2.3%	5	5.0%
Quality Control & Distribution	4	6.2%	0	0.0%	1	1.0%
Testing	1	1.6%	0	0.0%	1	1.0%
Process Controls	1	1.6%	1	1.1%	0	0.0%
Incoming Material	0	0.0%	0	0.0%	0	0.0%
Total	**64**	100%	**88**	100%	**100**	100%

Blood Derivatives Manufacturers

Manufacturing System	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Product Specifications	50	36.5%	54	45.4%	34	29.1%
Quality Control & Distribution	25	18.3%	22	18.5%	24	20.5%
Testing	7	5.1%	14	11.8%	19	16.2%
Incoming Material	14	10.2%	10	8.4%	14	12.0%
Labeling	23	16.8%	13	10.9%	13	11.1%
Process Controls	18	13.1%	6	5.0%	13	11.1%
Total	**137**	100%	**119**	100%	**117**	100%

In-Vitro Diagnostic Manufacturers

Manufacturing System	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Product Specifications	70	66.7%	49	52.7%	54	49.1%
Labeling	15	14.3%	15	16.1%	24	21.8%
Quality Control & Distribution	18	17.1%	24	25.8%	23	20.9%
Process Controls	2	1.9%	1	1.1%	5	4.6%
Testing	0	0.0%	4	4.3%	4	3.6%
Incoming Material	0	0.0%	0	0.0%	0	0.0%
Total	**105**	100%	**93**	100%	**110**	100%

Vaccine Manufacturers

Manufacturing System	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Product Specifications	92	47.4%	83	43.0%	128	50.2%
Quality Control & Distribution	44	22.7%	49	25.4%	70	27.5%
Process Controls	24	12.4%	24	12.4%	23	9.0%
Labeling	7	3.6%	12	6.2%	15	5.9%
Testing	23	11.9%	21	10.9%	10	3.9%
Incoming Material	4	2.0%	4	2.1%	9	3.5%
Total	**194**	100%	**193**	100%	**255**	100%

Licensed HCT/P Manufacturers (351 HCT/Ps)

Manufacturing System	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Labeling	15	44.1%	18	36.0%	16	50.0%
Product Specifications	10	29.4%	20	40.0%	7	21.9%
Testing	3	8.8%	1	2.0%	7	21.9%
Process Controls	1	2.9%	4	8.0%	1	3.1%
Incoming Material	2	5.9%	2	4.0%	1	3.1%
Quality Control & Distribution	3	8.8%	4	8.0%	0	0%
Receipt, Pre-Distribution Shipment, Distribution	0	0%	1	2.0%	0	0%
Total	**34**	100%	**50**	100%	**32**	100%

Gene Therapy Product Manufactures

Manufacturing System	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Testing	0	0%	1	33.3%	1	100%
Product Specifications	0	0%	2	66.7%	0	0%
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	0	0%	**3**	100%	**1**	100%

Table 4 shows the number of reports submitted each fiscal year for the past three years for 361 HCT/P manufacturers, with the data displayed separately for cellular 361 HCT/P manufacturers (e.g., hematopoietic stem/progenitor cells) and tissue 361 HCT/P manufacturers (e.g., skin, musculoskeletal, cornea). Combined, these manufacturers of 361 HCT/Ps submitted 1.3% of the total reports in FY20 and 66 fewer reports in FY20 compared to FY19. Manufacturers of cellular 361 HCT/Ps submitted 68% and manufacturers of tissue 361 HCT/Ps submitted 32% of the total 361 HCT/P deviation reports in FY20. Compared to FY19, manufacturers of cellular 361 HCT/Ps submitted 13 fewer reports and manufacturers of tissue 361 HCT/Ps submitted 53 fewer reports in FY20.

Table 4 - 361 HCT/P Manufacturers

Cellular 361 HCT/P Manufacturers

Manufacturing System	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Receipt, Pre-Distribution, Shipment & Distribution	118	78.7%	119	83.2%	109	83.8%
Processing & Processing Controls	15	10.0%	11	7.7%	11	8.5%
Recovery	0	0%	0	0%	4	3.1%
Supplies and Reagents	2	1.3%	3	2.1%	3	2.3%
Donor Testing	2	1.3%	2	1.4%	1	0.8%
Donor Eligibility	1	0.7%	1	0.7%	1	0.8%
Equipment	0	0%	0	0%	1	0.8%
Donor Screening	12	8.0%	6	4.2%	0	0%
Storage	0	0%	0	0%	0	0%
Labeling Controls	0	0%	0	0%	0	0%
Environmental Control	0	0%	1	0.7%	0	0%
Total	**150**	100%	**143**	100%	**130**	100%

Tissue 361 HCT/Ps Manufacturers

Manufacturing System	FY18 (#)	FY18 (%)	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Receipt, Pre-Distribution, Shipment & Distribution	22	23.7%	30	26.1%	20	32.3%
Donor Eligibility	33	35.5%	22	19.1%	14	22.6%
Donor Screening	6	6.5%	8	7.0%	9	14.5%
Donor Testing	11	11.8%	7	6.1%	8	12.9%
Processing & Processing Controls	6	6.5%	12	10.4%	4	6.5%
Supplies and Reagents	1	1.0%	1	0.9%	4	6.5%
Recovery	8	8.6%	31	27.0%	2	3.2%
Equipment	3	3.2%	2	1.7%	1	1.6%
Storage	2	2.2%	0	0%	0	0%
Labeling Controls	1	1.0%	2	1.7%	0	0%
Environmental Control	0	0%	0	0%	0	0%
Total	**93**	100%	**115**	100%	**62**	100%

In FY20, there were no changes to the HCT/P Deviation Codes. There was only a minor change in the Non-Blood BPD Codes, specifically adding "container" to QC-64-04. There were minimal changes to the Blood BPD Codes to clarify reportable events. However, as discussed above, the BPD reporting guidance issued March 2020 eliminated the reporting of post donation information, which decreased the number of total reports submitted by blood and Source Plasma establishments by 38%.

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 October 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 by 361 HCT/P Manufacturers

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

Tables 6 through 16 highlight the most frequent reports submitted in FY20 by each type of blood and Source Plasma establishment compared to reports submitted in FY19. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports listed in the table.

As discussed above, the guidance document for blood and Source Plasma establishments was updated March 2020, which eliminated reporting of PDI events. As a result, this policy change decreased the number of reports of PDI events submitted in FY20 by 53%.

Table 5 Post Donation Information Events

Establishment Type	FY19 (#)	FY19 (% of PD)	FY20 (#)	FY20 (% of PD)	% Decrease in Reports FY19 to FY20
Licensed Blood Establishments	11,358	32.4%	4,411	26.9%	61.2%
Unlicensed Blood Establishments	184	0.5%	110	0.7%	40.2%
Source Plasma Centers	23,544	67.1%	11,904	72.5%	49.4%
Total Reports	35,086	100%	16,425	100%	53.2%

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

Of the 9,769 reports submitted by licensed blood establishments in FY20 (Table 2), 1,823 reports (18.7%) involved quality control and distribution deviations or unexpected events (Table 6). The number of these reports increased 7% compared to FY19, which is an increase of 127 reports. There were 156 fewer reports submitted in FY20 compared to FY19 involving distributed units collected from a donor who subsequently tested confirmed positive for a relevant transfusion-transmitted infection. There were 166 more reports submitted in FY20 compared to FY19 involving bacterial detection testing.

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

QC & Distribution (QC)	FY19 (#)	FY19 (% of QC)	FY20 (#)	FY20 (% of QC)
Total QC Reports	**1,696**	**-**	**1,823**	**-**
Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease	***702***	***41.4%***	***546***	***30.0%***
HCV	214	12.6%	196	10.8%
HBV	147	8.7%	135	7.4%
Anti-HBc	55	3.2%	46	2.5%
Babesia	72	4.2%	69	3.8%
HIV	88	5.2%	67	3.7%
Chagas	58	3.4%	46	2.5%
West Nile Virus	79	4.7%	29	1.6%
Distribution of product that did not meet specifications	***426***	***25.1%***	***500***	***27.4%***
Product QC unacceptable, not performed, not documented, or incomplete	221	13.0%	271	14.9%
White Blood Cell count	105	6.2%	128	7.0%
RBC recovery	29	1.7%	33	1.8%
Platelet count	36	2.1%	28	1.5%
Product in which specification, other than QC, was not met	32	1.9%	48	2.6%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or documented	55	3.2%	40	2.2%
Outdated product	30	1.8%	36	2.0%
Product identified as unsuitable due to positive testing, event discovered subsequent to distribution	***310***	***18.3%***	***479***	***26.3%***
Bacterial testing	307	18.1%	473	25.9%
Shipping and storage	***117***	***6.9%***	***165***	***9.1%***
Distribution procedure not performed in accordance with blood bank transfusion service's specifications	***116***	***6.8%***	***109***	***6.0%***

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

Of the 9,769 reports submitted by licensed blood establishments in FY20 (Table 2), 1,586 reports (16.2%) involved donor screening deviations or unexpected events (Table 7). The number of these reports increased 31% compared to FY19, which is an increase of 376 reports. There were 500 more reports submitted in FY20 compared to FY19 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)	FY19 (#)	FY19 (% of DS)	FY20 (#)	FY20 (% of DS)
Total DS Reports	**1,210**	**-**	**1,586**	**-**
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***969***	***80.1%***	***1,383***	***87.2%***
Donor not previously deferred	783	64.7%	1,283	80.9%
Donor previously deferred due to history	115	9.5%	53	3.3%
Donor previously deferred due to testing	71	5.9%	47	3.0%
Donor record incomplete or incorrect	***131***	***10.8%***	***120***	***7.6%***
Donor history questions	125	10.3%	113	7.1%
Incorrect gender specific question asked, or incorrect answer documented	109	9.0%	96	6.1%
Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked	***96***	***7.9%***	***72***	***4.5%***
Travel to or resided in malaria endemic area/history of malaria	55	4.5%	38	2.4%
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel	19	1.6%	16	1.0%
Donor did not meet eligibility criteria	***14***	***1.2%***	***11***	***0.7%***

Of the 9,769 reports submitted by licensed blood establishments in FY20 (Table 2), 1,118 reports (11.4%) involved blood collection deviations or unexpected events (Table 8)**.** The number of these reports increased 29% compared to FY19, which is an increase of 250 reports. The number of reports involving clots or fibrin discovered in a product increased 24%.

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

Blood Collection (BC)	FY19 (#)	FY19 (% of BC)	FY20 (#)	FY20 (% of BC)
Total BC Reports	**868**	**-**	***1,118***	**-**
Collection process	***776***	***89.4%***	***984***	***88.0%***
Product contained clots or fibrin, not discovered prior to distribution	739	85.1%	918	82.1%
Product hemolyzed, not discovered prior to distribution	20	2.3%	53	4.7%
Sterility compromised	***74***	***8.5%***	***72***	***6.4%***
Bacterial contamination	67	7.7%	57	5.1%
Collection bag	***18***	***2.1%***	***60***	***5.4%***
Potential collection set defect	17	2.0%	59	5.3%

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

Of the 2,890 reports submitted by unlicensed registered blood establishments in FY20 (Table 2), 1,664 reports (57.6%) involved quality control and distribution deviations or unexpected events (Table 9). The number of these reports decreased 5% compared to FY19, which is a decrease of 83 reports.

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

QC & Distribution (QC)	FY19 (#)	FY19 (% of QC)	FY20 (#)	FY20 (% of QC)
Total QC Reports	**1,747**	**-**	**1,664**	**-**
Distribution procedure not performed in accordance with blood bank transfusion service's specifications	***1,533***	***87.8%***	***1487***	***89.4%***
Visual inspection not performed, not documented, or inadequate, includes product not documented or incorrectly documented as issued in the computer	653	37.4%	655	39.4%
Improper product selected for patient	192	11.0%	194	11.7%
Product not irradiated as required	212	12.1%	191	11.5%
Procedure for issuing not performed or documented in accordance with specifications	114	6.5%	120	7.2%
Improper ABO or Rh type selected for patient	133	7.6%	117	7.0%
Distribution of product that did not meet specifications	***157***	***9.0%***	***108***	***6.5%***
Product in which instrument QC, calibration, or validation unacceptable, incomplete or not documented	56	3.2%	32	1.9%
Outdated product	30	1.7%	25	1.5%
Product in which specification, other than QC, was not met	33	1.9%	22	1.3%
Product QC unacceptable, not performed, not documented or incomplete	18	1.0%	13	0.8%

Of the 2,890 reports submitted by unlicensed registered blood establishments in FY20 (Table 2), 542 reports (18.8%) involved labeling deviations or unexpected events (Table 10). The number of these reports decreased 13% compared to FY19, which is a decrease of 83 reports.

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

Labeling (LA)	FY19 (#)	FY19 (% of LA)	FY19 (#)	FY19 (% of LA)
Total LA Reports	**625**	**-**	**542**	**-**
Crossmatch tag, tie tag, or transfusion record incorrect or missing information	***389***	***62.2%***	***355***	***65.5%***
Recipient identification incorrect or missing	163	26.1%	163	30.1%
Crossmatch tag, tie tag, or transfusion record missing or attached to incorrect unit	60	9.6%	54	10.0%
Expiration date or time extended or missing	49	7.8%	38	7.0%
Unit or pool number incorrect or missing	27	4.3%	19	3.5%
Product type or code incorrect or missing	18	2.9%	19	3.5%
Labels applied to blood unit incorrect or missing information	***236***	***37.8%***	***187***	***34.5%***
Expiration date or time extended or missing	109	17.4%	101	18.6%
Irradiation status incorrect or missing	38	6.1%	25	4.6%
Product type or code incorrect or missing	28	4.5%	19	3.5%
Donor/unit number incorrect or missing	7	1.1%	9	1.7%
Combination of incorrect or missing information	15	2.4%	8	1.5%

Of the 2,890 reports submitted by unlicensed registered blood establishments in FY20 (Table 2), 460 reports (15.9%) involved routine testing deviations or unexpected events (Table 11). The number of these reports increased 4% compared to FY19, which was an increase of 18 reports. There were 72 more reports submitted in FY20 compared to FY19 involving ABO/Rh testing and 29 fewer reports submitted involving samples identification events.

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

Routine Testing (RT)	FY19 (#)	FY19 (% of RT)	FY20 (#)	FY20 (% of RT)
Total RT Reports	**442**	**-**	**460**	**-**
Testing performed, interpreted, or documented incorrectly; not performed; incompletely performed; or not documented	***376***	***85.1%***	***423***	***92.0%***
ABO and/or Rh	80	18.1%	152	33.0%
Antibody screening or identification	87	19.7%	91	19.8%
Compatibility	106	24.0%	88	19.1%
Antigen typing	71	16.1%	72	15.7%
Sample (used for testing) identification	***66***	***14.9%***	***37***	***8.0%***
Sample used for testing was incorrectly or incompletely labeled	35	7.9%	26	5.7%
Unsuitable sample used for testing (e.g., too old)	18	4.1%	7	1.5%
Incorrect sample tested	12	2.7%	4	0.9%

3. Most Frequent BPD Reports Submitted by Transfusion Services

Of the 1,785 reports submitted by transfusion services in FY20 (Table 2), 1,002 reports (56.1%) involved quality control and distribution deviations or unexpected events (Table 12). The number of these reports increased 2% compared to FY19, which was an increase of 22 reports.

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

QC & Distribution (QC)	FY19 (#)	FY19 (% of QC)	FY20 (#)	FY20 (% of QC)
Total QC Reports	**980**	**-**	**1,002**	**-**
Distribution procedure not performed in accordance with blood bank transfusion service's specifications	***871***	***88.9%***	***889***	***88.7%***
Visual inspection not performed, not documented, or inadequate, includes product not documented or incorrectly documented as issued in the computer	421	43.0%	384	38.4%
Product not irradiated as required	128	13.1%	125	12.5%
Improper product selected for patient	99	10.1%	113	11.3%
Procedure for issuing not performed or documented in accordance with specifications	71	7.2%	100	10.0%
Improper ABO or Rh type selected for patient	62	6.3%	62	6.2%
Distribution of product that did not meet specifications	***73***	***7.4%***	***71***	***7.1%***
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or not documented	33	3.4%	31	3.1%
Outdated product	28	2.9%	25	2.5%
Product distributed prior to resolution of discrepancy	2	0.2%	7	0.7%
Product in which specification, other than QC, not met	5	0.5%	5	0.5%
Shipping and storage	***33***	***3.4%***	***41***	***4.1%***
No documentation that product was stored at appropriate temperature	7	0.7%	21	2.1%
Product stored at incorrect temperature	8	0.8%	11	1.1%
Product was reissued without a record of proper temperature maintenance	14	1.4%	7	0.7%

Of the 1,785 reports submitted by transfusion services in FY20 (Table 2), 472 reports (26.4%) involved routine testing deviations or unexpected events (Table 13). The number of these reports decreased 17% compared to FY19, which was a decrease of 94 reports.

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

Routine Testing (RT)	FY19 (#)	FY19 (% of RT)	FY20 (#)	FY20 (% of RT)
Total RT Reports	**566**	**-**	**472**	**-**
Testing performed, interpreted, or documented incorrectly; not performed; incompletely performed; or not documented	***502***	***88.7%***	***424***	***89.8%***
Antigen typing	124	21.9%	113	23.9%
Compatibility	118	20.8%	105	22.2%
Antibody screening or identification	119	21.0%	94	19.9%
ABO and/or Rh typing	88	15.5%	77	16.3%
Sample (used for testing) identification	***64***	***11.3%***	***48***	***10.2%***
Sample used for testing was incorrectly or incompletely labeled	49	8.7%	31	6.6%
Incorrect sample tested	8	1.4%	9	1.9%
Unsuitable sample used for testing (e.g., too old)	6	1.1%	8	1.7%

Of the 1,785 reports submitted by transfusion services in FY20 (Table 2), 305 reports (17.1%) involved labeling deviations or unexpected events (Table 14). The number of these reports decreased 15% compared to FY19, which was a decrease of 52 reports. There were 40 fewer reports submitted in FY20 compared to FY19 involving recipient identification labeling.

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

Labeling (LA)	FY19 (#)	FY19 (% of LA)	FY20 (#)	FY20 (% of LA)
Total LA Reports	**357**	**-**	**305**	**-**
Crossmatch tag, tie tag or transfusion record incorrect or missing information	***282***	***79.0%***	***237***	***77.7%***
Recipient identification incorrect or missing	137	38.4%	97	31.8%
Crossmatch tag, tie tag, or transfusion record missing or attached to incorrect unit	42	11.8%	34	11.1%
Expiration date or time extended or missing	17	4.8%	17	5.6%
Unit or pool number incorrect or missing	8	2.2%	15	4.9%
Combination of incorrect or missing information	10	2.8%	14	4.6%
Compatibility information incorrect or missing	7	2.0%	13	4.3%
Product type or code incorrect or missing	18	5.0%	12	3.9%
Labels applied to blood unit incorrect or missing information	***75***	***21.0%***	***68***	***22.3%***
Expiration date or time extended or missing	36	10.1%	39	12.8%
Combination of incorrect or missing information	12	3.4%	11	3.6%
Product type or code incorrect or missing	3	0.8%	8	2.6%
Product volume incorrect or missing	7	2.0%	6	2.0%

4. Most Frequent BPD Reports Submitted by Source Plasma Establishments

Of the 15,678 reports submitted by Source Plasma establishments in FY20 (Table 2), 3,173 reports (20.2%) involved quality control and distribution deviations or unexpected events (Table 15)**.** The number of these reports decreased 12% compared to FY19, which was a decrease of 414 reports. The number of reports related to a donor subsequently testing positive for HCV decreased from 1,809 in FY19 to 1,510 in FY20.

Table 15 - Most Frequent BPD Reports - Quality Control & Distribution from Source Plasma Establishments

QC & Distribution (QC)	FY19 (#)	FY19 (% of QC)	FY20 (#)	FY20 (% of QC)
Total QC Reports	**3,587**	**-**	**3,173**	**-**
Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease	***3,490***	***97.3%***	***3,072***	***96.8%***
HCV	1,809	50.4%	1,510	47.6%
HBV	1,150	32.1%	1,055	33.2%
HIV	521	14.5%	494	15.6%
Distribution of product that did not meet specifications	***37***	1.0%	***56***	***1.8%***
Product identified as unsuitable due to a donor screening deviation or unexpected event	23	0.6%	31	1.0%
Product identified as unsuitable due to a collection deviation or unexpected event	8	0.2%	18	0.6%
Failure to quarantine unit due to medical history	***26***	***0.7%***	***35***	***1.1%***
Post donation illness	6	0.2%	15	0.5%
Donor received tattoo and/or piercing	12	0.3%	9	0.3%

Of the 15,678 reports submitted by Source Plasma establishments in FY20 (Table 2), 540 reports (3.4%) involved donor screening deviations or unexpected events (Table 16). The number of these reports increased 57% compared to FY19, which was an increase of 197 reports. There were 96 more reports submitted in FY20 compared to FY19 involving donor history questions incorrect or incomplete, with most reports related to incorrect gender specific questions. There were 78 more reports submitted in FY20 compared to FY19 involving a donor providing history which warranted deferral or follow up and was not deferred.

Table 16 - Most Frequent BPD Reports - Donor Screening from Source Plasma Establishments

Donor Screening (DS)	**FY19 (#)**	**FY19 (% of DS)**	**FY20 (#)**	**FY20 (% of DS)**
Total DS Reports	**343**	**-**	**540**	**-**
Donor record incomplete or incorrect	***203***	***59.2%***	***298***	***55.2%***
Donor history questions	171	49.9%	267	49.4%
Incorrect gender specific question asked or incorrect answer	88	25.7%	184	34.1%
Donor comprehension	79	23.0%	66	12.2%
Donor identification	32	9.3%	31	5.7%
Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked	***26***	***7.6%***	***104***	***19.3%***
Other (unacceptable address)	7	2.0%	52	9.6%
Donor received tattoo and/or piercing	12	3.5%	33	6.1%
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***54***	***15.7%***	***101***	***18.7%***
Donor not previously deferred	51	14.9%	95	17.6%
Donor previously deferred due to history	3	0.9%	6	1.1%
Donor did not meet eligibility criteria	***60***	***17.5%***	***37***	***10.8%***
Medical history interview or physical assessment not performed or inadequate	59	17.2%	35	6.5%

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

Tables 17 through 22 highlight the most frequent reports submitted in FY20 by each type of licensed non-blood manufacturer compared to reports submitted in FY19. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports listed in the table.

Of the 100 reports submitted by allergenic manufacturers in FY20 (Table 3), 93% of the reports were related to product specifications (Table 17).

Table 17 - Most Frequent BPD Reports Submitted by Allergenic Manufacturers

Allergenic Manufacturers	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Total Reports	**88**	-	**100**	-
Product Specifications	***85***	***96.6%***	***93***	***93.0%***
Product specification not met; contains precipitate	80	90.9%	86	***86.0%***

Of the 117 reports submitted by blood derivative manufacturers in FY20 (Table 3), 29% of the reports were related to product specifications and 21% of the reports were related to quality control and distribution (Table 18).

Table 18 - Most Frequent BPD Reports Submitted by Blood Derivative Manufacturers

Blood Derivative Manufacturers	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Total Reports	**119**	-	**117**	-
Product Specifications	***54***	***45.4%***	***34***	***29.1%***
Stability testing failed	20	16.8%	12	10.3%
Appearance	6	5.0%	5	4.3%
Potency	9	7.6%	3	2.6%
Component packaged with final product did not meet specifications	17	14.3%	13	11.1%
Broken/cracked vial	12	10.1%	6	5.1%
Contains precipitate/particle	2	1.7%	6	5.1%
Quality Control and Distribution	***22***	***18.5%***	***24***	***20.5%***
Packing; Broken or cracked vial/syringe	14	11.8%	21	17.9%

Of the 110 reports submitted by in-vitro diagnostic manufacturers in FY20 (Table 3), 49% of the reports were related to product specifications and 22% of the reports were related to labeling (Table 19).

Table 19 - Most Frequent BPD Reports Submitted by In-Vitro Diagnostic Manufacturers

In-Vitro Diagnostic Manufacturers	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Total Reports	**93**	**-**	**110**	**-**
Product Specifications	***49***	***52.7%***	***54***	***49.1%***
Product specification not met; Unexpected positive, negative, or weak reactions in testing	29	31.2%	36	32.7%
Product specification not met; Container closure not secure or damaged	8	8.6%	11	10.0%
Labeling	***15***	***16.1%***	***24***	***21.8%***
Package insert	4	4.3%	7	6.4%
Product label	3	3.2%	5	4.5%
Multiple information	3	3.2%	5	4.5%
Quality Control and Distribution	***24***	***25.8%***	***23***	***20.9%***
Packing	18	19.4%	15	13.6%

Of the 255 reports submitted by vaccine manufacturers in FY20 (Table 3), 50% of the reports were related to product specifications and 28% of the reports were related to quality control and distribution (Table 20). The number of reports involving product specification increased from 71 in FY19 to 121 in FY20, specifically related to appearance and container closure.

Table 20 - Most Frequent BPD Reports Submitted by Vaccine Manufacturers

Vaccine Manufacturers	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Total Reports	**193**	**-**	**255**	**-**
Product Specifications	***83***	***43.0%***	***128***	***50.2%***
Product specification not met	71	36.8%	121	47.5%
Appearance	33	17.1%	52	20.4%
Container closure not secure or damaged	27	14.0%	56	22.0%
Quality Control and Distribution	***49***	***25.4%***	***70***	***27.5%***
Packing; Broken or cracked vial/syringe	49	25.4%	67	26.3%

Of the 32 reports submitted by licensed HCT/P manufacturers (351 HCT/Ps) in FY20 (Table 3), 50% of the reports were related to labeling (Table 21). The number of reports involving contamination with a microorganism decreased from 19 in FY19 to five in FY20.

Table 21 - Most Frequent BPD Reports Submitted by Licensed HCT/P Manufacturers (351 HCT/Ps)

Licensed HCT/P Manufacturers (351 HCT/Ps)	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Total Reports	**50**	**-**	**32**	**-**
Labeling	***18***	***26.0%***	***16***	***50.0%***
Product label; incorrect/illegible; recipient identification	12	24.0%	16	50.0%
Product Specifications	***20***	***40.0%***	***7***	***21.9%***
Product specification not met; contaminated with microorganism	19	38.0%	5	15.6%
Testing	***1***	***2.0%***	***7***	***21.9%***
Safety	0	0.0%	4	12.5%

Only one report was submitted by a gene therapy manufacturer in FY20 (Table 3), which was related to testing (Table 22).

Table 22 - Most Frequent BPD Reports Submitted by Gene Therapy Manufacturers

Licensed Gene Therapy Manufacturers	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Total Reports	**3**	**-**	**1**	**-**
Testing	***1***	***33.3%***	***1***	***100.0%***

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

Tables 23 and 24 highlight the most frequent reports submitted in FY20 by each type of 361 HCT/P manufacturer compared to reports submitted in FY19. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports listed in the table.

Of the 130 reports submitted by cellular 361 HCT/P manufacturers in FY20 (Table 4), 84% of the reports involved receipt, pre-distribution, shipment and distribution and 9% of the reports involved processing and process controls (Table 23).

Table 23 - Most Frequent HCT/P Deviation Reports Submitted by Cellular 361 HCT/Ps Manufacturers

Cellular 361 HCT/Ps Manufacturers	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Total Reports	**143**	**-**	**130**	**-**
Receipt, Pre-Distribution, Shipment & Distribution	***119***	***83.2%***	***109***	***83.8%***
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	117	81.8%	103	79.2%
Processing & Processing Controls	***11***	***7.7%***	***11***	***8.5%***
Processing; HCT/P contaminated, potentially contaminated, or cross-contaminated during processing	6	4.2%	7	5.4%

Of the 62 reports submitted by tissue 361 HCT/P manufacturers in FY20 (Table 4), 32% of the reports involved receipt, pre-distribution, shipment and distribution and 23% of the reports involved donor eligibility (Table 24). The number of reports involving recovery decreased from 31 reports in FY19 to two reports in FY20. One report submitted in FY20 and 31 reports submitted in FY19 involved eye tissue recovered using an eyewash that was recalled due to potential contamination.

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

Tissue 361 HCT/Ps Manufacturers	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)
Total Reports	**115**		**62**	
Receipt, Pre-Distribution, Shipment & Distribution	***30***	***26.1%***	***20***	***32.3%***
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	21	18.3%	13	21.0%
Donor Eligibility	***22***	***19.1%***	***14***	***22.6%***
Ineligible donor accepted; Risk factors for, or clinical evidence of infection due to RCDAD	19	16.5%	13	21.0%
Final autopsy results received post distribution	5	4.3%	6	9.7%
Donor Screening	***8***	***7.0%***	***9***	***14.5%***
Donor screening not performed or performed incorrectly	8	***7.0%***	9	14.5%
Recovery	***31***	***27.0%***	***2***	3.2%
Manner of recovery; HCT/P contaminated, potentially contaminated, or cross-contaminated during recovery	31	27.0%	2	3.2%