Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please call 800-835-4709 or 240-402-8010, extension 1. CBER Consumer Affairs Branch or send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

Biological Product and HCT/P Deviation Reports

Annual Summary for Fiscal Year 2024

Table of Contents

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) described in 21 CFR 1271.10 and regulated by FDA solely under section 361 of the Public Health Service Act and 21 CFR Part 1271 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 related to the prevention of communicable disease transmission or HCT/P contamination [21 CFR 1271.350(b)]. 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 Biological Product Deviation Guidances & Rules | FDA. A guidance document for deviation reporting for 361 HCT/Ps (Ref. 3) is available at 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 | FDA.

This annual summary report provides an overview of the reports submitted during the fiscal year encompassing October 1, 2023, through September 30, 2024 (FY24), 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 FY24 to FY23, whereas Tables 1 through 4 below also include comparative data for FY22. Previous summary reports are available at
Biological Product Deviation Reports Annual Summaries | FDA. Our system does not collect the necessary denominator data to calculate genuine rates when evaluating possible trends.

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 16,993 reports submitted during FY24, this summary excludes data for deviation 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 FY24 (16,993) increased 4.5% compared to FY23 (16,258). The total number of reporting establishments increased from 2,432 in FY23 to 2,611 in FY24. Compared to FY23, there were 182 more blood and Source Plasma establishments, two more manufacturers of licensed biological products other than blood and blood components, and five fewer 361 HCT/P manufacturers reporting in FY24.

Table 1 - Total Deviation Reports FY22 – FY24

Establishment Type	Number of Reporting Establishments			Total Reports Submitted			*Potential* Recalls		
	FY22	FY23	FY24	FY22	FY23	FY24	FY22	FY23	FY24
Blood/Source Plasma Manufacturers									
Licensed Blood Establishments	188(72*)	191(68*)	188(70*)	6,131	5,864	5,570	422	372	378
Unlicensed Blood Establishments[1]	328	330	331	2,429	2,637	*2,782*	13	8	19
Transfusion Services[2]	722	768	849	1,875	2,173	2,561	0	0	0
Source Plasma Establishments	875(17*)	984(18*)	1,087(22*)	3,848	4,904	5,365	0	0	0
Sub-Total	*2,113*	*2,273*	*2,455*	*14,283*	*15,578*	*16,278*	*435*	*380*	*397*
Licensed Non-Blood Manufacturers									
Allergenic	4(4*)	3(3*)	4(4*)	81	89	88	0	2	1
Blood Derivative	27(18*)	23(17*)	24(15*)	92	63	90	2	0	1
In Vitro Diagnostic	14(13*)	9(9*)	13(12*)	87	79	66	0	3	8
Vaccine	25(23*)	20(18*)	19(18*)	201	194	225	2	6	2
Gene Therapy Products	4(4*)	8(7*)	6(6*)	18	18	17	0	0	1
351 HCT/P	4(3*)	5(4*)	4(4*)	25	18	17	0	0	0
Sub-Total	*78(65*)*	*68(58*)*	*70(59*)*	*504*	*461*	*503*	*4*	*11*	*13*
361 HCT/P Manufacturers									
Cellular HCT/P	44	53	50	134	134	128	0	0	0
Tissue HCT/P	41	38	36	89	85	84	25	33	18
Sub-Total	*85*	*91*	*86*	*223*	*219*	*212*	*25*	*33*	*18*
Total	**2,276**	**2,432**	**2,611**	**15,010**	**16,258**	**16,993**	**464**	**424**	**428**

[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 and Source Plasma establishments submitted 96% of the total reports in FY24 and 700 more reports in FY24 compared to FY23 (Table 1). Table 2 shows the number of reports submitted each fiscal year for the past three years by each type of establishments. Licensed blood establishments submitted 34%, unlicensed registered blood establishments submitted 17%, transfusion services submitted 16%, and Source Plasma establishments submitted 33% of the total blood and Source Plasma reports in FY24. Compared to FY23, licensed blood establishments submitted 294 fewer reports (5.0% decrease), unlicensed registered blood establishments submitted 145 more reports (5.5% increase), transfusion

services submitted 388 more reports (17.9% increase), and Source Plasma establishments submitted 461 more reports (9.4% increase) in FY24.

Table 2 - Blood and Source Plasma Establishments

Licensed Blood Establishments

Manufacturing System	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
QC & Distribution	2,328	38.0%	2,425	41.4%	2,403	43.1%
Blood Collection	1,785	29.1%	1,484	25.3%	1,388	24.9%
Donor Screening	1,118	18.2%	1,081	18.4%	946	17.0%
Labeling	326	5.3%	334	5.7%	364	6.5%
Routine Testing	230	3.8%	240	4.1%	230	4.1%
Component Preparation	230	3.8%	226	3.9%	190	3.4%
Transfusion-Transmitted Infection Testing	86	1.4%	63	1.1%	41	0.7%
Donor Deferral	28	0.5%	11	0.2%	8	0.1%
Total	**6,131**	100%	**5,864**	100%	**5,570**	100%

Unlicensed Blood Establishments

Manufacturing System	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
QC & Distribution	1,463	60.2%	1,607	60.9%	1,712	61.5%
Routine Testing	426	17.5%	475	18.0%	509	18.3%
Labeling	467	19.2%	455	17.3%	442	15.9%
Component Preparation	54	2.2%	76	2.9%	73	2.6%
Donor Screening	6	0.2%	3	0.1%	26	0.9%
Transfusion-Transmitted Infection Testing	5	0.2%	12	0.5%	12	0.4%
Blood Collection	6	0.2%	7	0.3%	6	0.2%
Donor Deferral	2	0.1%	2	<0.1%	2	<0.1%
Total	**2,429**	100%	**2,637**	100%	**2,782**	100%

Transfusion Services

Manufacturing System	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
QC & Distribution	1,018	54.3%	1,196	55.0%	1,456	56.9%
Routine Testing	535	28.5%	607	27.9%	701	27.4%
Labeling	313	16.7%	361	16.6%	394	15.4%
Component Preparation	7	0.4%	8	0.4%	10	0.4%
Transfusion-Transmitted Infection Testing*	2	0.1%	1	<0.1%	0	0.0%
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	**1,875**	100%	**2,173**	100%	**2,561**	100%

**Bacterial detection testing*

Source Plasma Establishments

Manufacturing System	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
QC & Distribution	3,433	89.2%	4,372	89.2%	4,824	89.9%
Donor Screening	395	10.3%	459	9.4%	459	8.6%
Blood Collection	11	0.3%	42	0.9%	53	1.0%
Transfusion-Transmitted Infection Testing	4	0.1%	6	0.1%	24	0.4%
Donor Deferral	5	0.1%	24	0.5%	4	<0.1%
Labeling	0	0.0%	1	<0.1%	1	<0.1%
Component Preparation	0	0.0%	0	0.0%	0	0.0%
Routine Testing	0	0.0%	0	0.0%	0	0.0%
Total	**3,848**	100%	**4,904**	100%	**5,365**	100%

Manufacturers of licensed non-blood products submitted 3% of the total reports in FY24 and 42 more reports in FY24 compared to FY23 (Table 1). Table 3 shows the number of reports submitted each fiscal year for the past three years for each type of manufacturer. Allergenic manufacturers submitted 17%, plasma derivative manufacturers submitted 18%, in-vitro diagnostic manufacturers submitted 13%, vaccine manufacturers submitted 45%, gene therapy product manufacturers submitted 3%, and licensed HCT/P manufacturers (351 HCT/Ps) submitted 3% of the total licensed non-blood reports in FY24. Compared to FY23, allergenic manufacturers submitted one fewer report, plasma derivative manufacturers submitted 27 more reports, in-vitro diagnostic manufacturers submitted 13 fewer reports, vaccine manufacturers submitted 31 more reports, gene therapy product manufacturers submitted one fewer report, and licensed HCT/P manufacturers submitted one fewer report in FY24.

Table 3 - Licensed Non-Blood Manufacturers

Allergenic Manufacturers

Manufacturing System	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Product Specifications	78	96.3%	81	91.0%	77	87.5%
Labeling	2	2.5%	4	4.5%	10	11.4%
Testing	1	1.2%	1	1.1%	1	1.1%
Process Controls	0	0.0%	2	2.2%	0	0.0%
Incoming Material	0	0.0%	1	1.1%	0	0.0%
Quality Control & Distribution	0	0.0%	0	0.0%	0	0.0%
Total	**81**	100%	**89**	100%	**88**	100%

Blood Derivatives Manufacturers

Manufacturing System	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Process Controls	20	21.7%	15	23.8%	27	30.0%
Quality Control & Distribution	19	20.7%	14	22.2%	23	25.6%
Product Specifications	32	34.8%	20	31.7%	20	22.2%
Testing	10	10.9%	8	12.7%	13	14.4%
Incoming Material	3	3.3%	2	3.2%	4	4.4%
Labeling	8	8.7%	4	6.4%	3	3.3%
Total	**92**	100%	**63**	100%	**90**	100%

In-Vitro Diagnostic Manufacturers

Manufacturing System	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Product Specifications	24	27.6%	34	43.0%	27	40.9%
Quality Control & Distribution	30	34.5%	16	20.3%	15	22.7%
Labeling	17	19.5%	12	15.2%	13	19.7%
Incoming Material	7	8.0%	7	8.9%	7	10.6%
Process Controls	2	2.3%	4	5.0%	4	6.1%
Testing	7	8.0%	6	7.6%	0	0.0%
Total	**87**	100%	**79**	100%	**66**	100%

Vaccine Manufacturers

Manufacturing System	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Product Specifications	86	42.8%	67	34.5%	79	35.1%
Quality Control & Distribution	43	21.4%	54	27.8%	68	30.2%
Incoming Material	25	12.4%	24	12.4%	28	12.4%
Process Controls	27	13.4%	18	9.3%	19	8.4%
Labeling	12	6.0%	17	8.8%	18	8.0%
Testing	8	4.0%	14	7.2%	13	5.8%
Total	**201**	100%	**194**	100%	**225**	100%

Gene Therapy Product Manufactures

Manufacturing System	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Testing	5	27.8%	9	50.0%	7	41.2%
Incoming Material	3	16.7%	2	11.1%	3	17.6%
Labeling	1	5.6%	0	0.0%	3	17.6%
Process Controls	1	5.6%	4	22.2%	2	11.8%
Product Specifications	6	33.3%	2	11.1%	1	5.9%
Quality Control & Distribution	2	11.1%	1	5.6%	1	5.9%
Total	**18**	100%	**18**	100%	**17**	100%

Licensed HCT/P Manufacturers (351 HCT/Ps)

Manufacturing System	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Labeling	20	80.0%	6	33.3%	5	29.4%
Product Specifications	2	8.0%	5	27.8%	4	23.5%
Testing	0	0.0%	5	27.8%	3	17.6%
Incoming Material	1	4.0%	1	5.6%	3	17.6%
Process Controls	2	8.0%	1	5.6%	1	5.9%
Quality Control & Distribution	0	0.0%	0	0.0%	1	5.9%
Total	**25**	100%	**18**	100%	**17**	100%

Manufacturers of 361 HCT/Ps submitted 1% of the total reports in FY24 and seven fewer reports in FY24 compared to FY23 (Table 1). Table 4 shows the number of reports submitted each fiscal year for the past three years by 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). Manufacturers of cellular 361 HCT/Ps submitted 60% and manufacturers of tissue 361 HCT/Ps submitted 40% of the total 361 HCT/P deviation reports in FY24. Compared to FY23, manufacturers of cellular 361 HCT/Ps submitted six fewer reports and manufacturers of tissue 361 HCT/Ps submitted one fewer report in FY24.

Table 4 - 361 HCT/P Manufacturers

Cellular 361 HCT/P Manufacturers

Manufacturing System	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Receipt, Pre-Distribution, Shipment & Distribution	91	67.9%	100	74.6%	105	82.0%
Processing & Processing Controls	24	17.9%	16	11.9%	15	11.7%
Facilities	3	2.2%	6	4.5%	3	2.3%
Supplies and Reagents	5	3.7%	4	3.0%	2	1.6%
Storage	6	4.5%	2	1.5%	2	1.6%
Recovery	1	0.7%	4	3.0%	1	0.8%
Donor Screening	2	1.5%	1	0.7%	0	0.0%
Equipment	1	0.7%	1	0.7%	0	0.0%
Environmental Control	1	0.7%	0	0.0%	0	0.0%
Donor Testing	0	0.0%	0	0.0%	0	0.0%
Donor Eligibility	0	0.0%	0	0.0%	0	0.0%
Labeling Controls	0	0.0%	0	0.0%	0	0.0%
Total	**134**	100%	**134**	100%	**128**	100%

Tissue 361 HCT/Ps Manufacturers

Manufacturing System	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Donor Eligibility	37	41.6%	14	14.7%	47	56.0%
Receipt, Pre-Distribution, Shipment & Distribution	18	20.2%	40	42.1%	12	14.3%
Donor Testing	11	12.4%	16	16.8%	11	13.1%
Processing & Processing Controls	11	12.4%	4	4.2%	6	7.1%
Recovery	2	2.2%	0	0.0%	3	3.6%
Storage	1	1.1%	1	1.1%	2	2.4%
Donor Screening	7	7.9%	18	18.9%	1	1.2%
Labeling Controls	1	1.1%	2	2.1%	1	1.2%
Supplies and Reagents	1	1.1%	0	0.0%	1	1.2%
Environmental Control	0	0.0%	0	0.0%	0	0.0%
Equipment	0	0.0%	0	0.0%	0	0.0%
Facilities	0	0.0%	0	0.0%	0	0.0%
Total	**89**	100%	**95**	100%	**84**	100%

In FY24, there were no changes to the Non-Blood BPD Codes or the HCT/P Deviation Codes. The Blood BPD Codes were modified for consistency with the May 2023 guidance (Guidance for Industry: Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products.

You may submit questions concerning this summary to CBER at bp_deviations@fda.hhs.gov or hctp_deviations@fda.hhs.gov.

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 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 | FDA

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 5 through 15 highlight the most frequent reports submitted in FY24 by each type of blood and Source Plasma establishment compared to reports submitted in FY23. 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.

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

Of the 5,570 reports submitted by licensed blood establishments in FY24 (Table 2), 2,403 reports (43.1%) involved quality control and distribution deviations or unexpected events (Table 5). The number of these reports decreased 1% compared to FY23, which is a decrease of 22 reports. There were 94 fewer reports involving the distribution of product that did not meet specifications. There were 29 fewer reports submitted in FY24 compared to FY23 involving a positive bacterial detection test result. *Cutibacterium acnes* was identified as the organism in 349 (65%) of the 537 reports regarding bacterial testing submitted in FY24. There were 78 more reports submitted in FY24 compared to FY23 involving distributed units collected from a donor who subsequently tested confirmed positive for a relevant transfusion-transmitted infection. There was an increase of 79 reports involving products collected from a donor who subsequently tested confirmed positive for Babesia.

Table 5 - Most Frequent BPD Reports - Quality Control & Distribution from Licensed Blood Establishments

QC & Distribution (QC)	FY23 (#)	FY23 (% of QC)	FY24 (#)	FY24 (% of QC)
Total QC Reports	**2,425**		**2,403**	
Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease	***1,051***	***43.3%***	***1,129***	***47.0%***
Babesia	383	15.8%	462	19.2%
HBV	270	11.1%	229	9.5%
Anti-HBc	163	6.7%	125	5.2%
HCV	190	7.8%	201	8.4%
West Nile Virus	133	5.5%	166	6.9%
HIV	63	2.6%	69	2.9%
Product identified as unsuitable due to positive testing; event discovered subsequent to distribution	***572***	***23.6%***	***538***	***22.4%***
Bacterial testing	566	23.3%	537	22.3%
Distribution of product that did not meet specifications	***534***	***22.0%***	***440***	***18.3%***
Product QC unacceptable, not performed, not documented, or incomplete	241	9.9%	164	6.8%
White Blood Cell count	78	3.2%	67	2.8%
Hematocrit/Hemoglobin	72	3.0%	27	1.1%
Platelet count/yield	26	1.1%	16	0.7%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or documented	69	2.8%	63	2.6%
Product in which specification, other than QC, was not met	50	2.1%	54	2.2%
Product identified as unsuitable due to a collection deviation or unexpected event	38	1.6%	53	2.2%

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

Of the 5,570 reports submitted by licensed blood establishments in FY24 (Table 2), 1,388 reports (24.9%) involved blood collection deviations or unexpected events (Table 6)**.** The number of these reports decreased 6.5% compared to FY23, which is a decrease of 96 reports. The number of reports involving clots or fibrin discovered in a product decreased 10.8%. There was a 7.2% decrease in reports of clots or fibrin discovered in frozen products after thawing (FY23-1,030; FY24-956).

Table 6 - Most Frequent BPD Reports – Blood Collection from Licensed Blood Establishments

Blood Collection (BC)	FY23 (#)	FY23 (% of BC)	FY24 (#)	FY24 (% of BC)
Total BC Reports	**1,484**	**-**	**1,388**	**-**
Collection process	***1,322***	***89.1%***	***1,205***	***86.8%***
Product contained clots or fibrin, not discovered prior to distribution	1,256	84.6%	1,120	80.7%
Product hemolyzed, not discovered prior to distribution	46	3.1%	72	5.2%
Collection bag	***101***	***6.8%***	***103***	***7.4%***
Potential collection set defect	98	6.6%	101	7.3%
Sterility compromised	***60***	***4.0%***	***77***	***5.5%***
Bacterial contamination	30	2.0%	58	4.2%

Of the 5,570 reports submitted by licensed blood establishments in FY24 (Table 2), 946 reports (17,0%) involved donor screening deviations or unexpected events (Table 7). The number of these reports decreased 12.5% compared to FY23, which is a decrease of 135 reports. The number of reports involving deferral screening not done or incorrectly performed decreased 10.4% compared to FY23.

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

Donor Screening (DS)	FY23 (#)	FY23 (% of DS)	FY24 (#)	FY24 (% of DS)
Total DS Reports	**1,081**	**-**	**946**	**-**
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***914***	***84.6%***	***819***	***86.6%***
Donor not previously deferred	849	78.5%	761	80.4%
Donor previously deferred due to testing	44	4.1%	36	3.8%
Donor previously deferred due to history	21	1.9%	22	2.3%
Donor record incomplete or incorrect	***125***	***11.6%***	***75***	***7.9%***
Donor history questions	118	10.9%	69	7.3%
Incorrect gender specific question asked, or incorrect answer documented	99	9.2%	39	4.1%
Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked	***36***	***3.3%***	***45***	***4.8%***
Travel to or resided in malaria endemic area/history of malaria	24	2.2%	32	3.4%

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

Of the 2,782 reports submitted by unlicensed registered blood establishments in FY24 (Table 2), 1,712 reports (61.5%) involved quality control and distribution deviations or unexpected events (Table 8)**.** The number of these reports increased 6.5% compared to FY23, which is an increase of 105 reports. The number of reports involving visual inspection not performed increased 11.9% compared to FY23.

Table 8 - Most Frequent BPD Reports - Quality Control & Distribution from Unlicensed Registered Blood Establishments

QC & Distribution (QC)	FY23 (#)	FY23 (% of QC)	FY23 (#)	FY23 (% of QC)
Total QC Reports Received	***1,607***	**-**	***1,712***	**-**
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***1,414***	***88.0%***	***1,508***	***88.1%***
Visual inspection not performed, not documented, or inadequate, includes product not documented or incorrectly documented as issued in the computer	655	40.8%	733	42.8%
Product not irradiated as required	178	11.1%	186	10.9%
Improper product selected for patient	186	11.6%	180	10.5%
Improper ABO or Rh type selected for patient	121	7.5%	156	9.1%
Procedure for issuing not performed or documented in accordance with specifications	59	3.7%	47	2.7%
Product issued to wrong patient	67	4.2%	42	2.5%
Distribution of product that did not meet specifications	***132***	***8.2%***	***130***	***7.6%***
Product in which instrument QC, calibration, or validation unacceptable, incomplete, or not documented	49	3.0%	50	2.9%
Outdated product	21	1.3%	29	1.7%
Product in which specification, other than QC, was not met	23	1.4%	25	1.5%
Shipping and storage	***51***	***3.2%***	***57***	***3.3%***
No documentation that product was stored at appropriate temperature	14	0.9%	17	1.0%
Product shipped at incorrect temperature	13	0.8%	15	0.9%
Product was reissued without a record of proper temperature maintenance	14	0.9%	13	0.8%

Of the 2,782 reports submitted by unlicensed registered blood establishments in FY24 (Table 2), 509 reports (18.3%) involved routine testing deviations or unexpected events (Table 9). The number of these reports increased 7.2% compared to FY23, which was an increase of 34 reports. Compared to FY23, there were 46 more reports involving compatibility testing and 26 fewer reports involving ABO/Rh testing submitted in FY24.

Table 9 - Most Frequent BPD Reports - Routine Testing from Unlicensed Registered Blood Establishments

Routine Testing (RT)	FY23 (#)	FY23 (% of RT)	FY24 (#)	FY24 (% of RT)
Total RT Reports	**475**	**-**	**509**	**-**
Testing performed, interpreted, or documented incorrectly; not performed; incompletely performed; or not documented	***435***	***91.6%***	***451***	***88.6%***
Compatibility	88	18.5%	134	26.3%
Antigen typing	100	21.1%	94	18.5%
Antibody screening or identification	93	19.6%	93	18.3%
ABO and/or Rh	112	23.6%	86	16.9%
Sample (used for testing) identification	***47***	***9.9%***	***58***	***11.4%***
Sample used for testing was incorrectly or incompletely labeled	27	5.7%	36	7.1%
Unsuitable sample used for testing (e.g., too old)	13	2.7%	17	3.3%
Incorrect sample tested	7	1.5%	5	1.0%

Of the 2,782 reports submitted by unlicensed registered blood establishments in FY24 (Table 2), 442 reports (15.9%) involved labeling deviations or unexpected events (Table 10). Compared to FY23, there were 13 fewer reports submitted in FY24 involving labeling.

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

Labeling (LA)	FY23 (#)	FY23 (% of LA)	FY24 (#)	FY24 (% of LA)
Total LA Reports Received	**455**	**-**	**442**	**-**
Crossmatch tag, tie tag, to transfusion record incorrect or missing information	***260***	***57.1%***	***260***	***58.8%***
Recipient identification incorrect or missing	84	18.5%	77	17.4%
Crossmatch tag, tie tag, or transfusion record incorrect or missing or attached to incorrect unit	63	13.8%	56	12.7%
Expiration date or time extended or missing	28	6.2%	31	7.0%
Compatibility information incorrect or missing	19	4.2%	18	4.1%
Combination of incorrect or missing information	11	2.4%	18	4.1%
Antigen incorrect or missing	12	2.6%	13	2.9%
Product volume incorrect or missing	6	1.3%	13	2.9%
Unit or pool number incorrect or missing	12	2.6%	10	2.3%
Labels applied to blood unit incorrect or missing information	***193***	***42.4%***	***181***	***41.0%***
Expiration date or time extended or missing	110	24.2%	83	18.8%
Irradiation status incorrect or missing	29	6.4%	24	5.4%
Product type or code incorrect or missing	16	3.5%	23	5.2%
Combination of incorrect or missing information	12	2.6%	22	5.0%

3. Most Frequent BPD Reports Submitted by Transfusion Services

Of the 2,561 reports submitted by transfusion services in FY24 (Table 2), 1,456 reports (56.9%) involved quality control and distribution deviations or unexpected events (Table 11). The number of these reports increased 21.7% compared to FY23, which was an increase of 260 reports. The number of reports involving visual inspection not performed increased 13.4% compared to FY23.

Table 11 - Most Frequent BPD Reports - Quality Control & Distribution from Transfusion Services

QC & Distribution (QC)	FY23 (#)	FY23 (% of QC)	FY24 (#)	FY24 (% of QC)
Total QC Reports Received	**1,196**	**-**	**1,456**	**-**
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***1,077***	***90.1%***	***1,276***	***87.6%***
Visual inspection not performed, not documented, or inadequate, includes product not documented or incorrectly documented as issued in the computer	545	45.6%	618	42.4%
Product not irradiated as required	126	10.5%	158	10.9%
Improper product selected for patient	73	6.1%	124	8.5%
Improper ABO or Rh type selected for patient	118	9.9%	108	7.4%
Procedure for issuing not performed or documented in accordance with specifications	68	5.7%	106	7.3%
Distribution of product that did not meet specifications	***92***	***7.7%***	***122***	***8.4%***
Outdated product	28	2.3%	44	3.0%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or not documented	36	3.0%	38	2.6%
Shipping and storage	***26***	***2.2%***	***50***	***3.4%***

Of the 2,561 reports submitted by transfusion services in FY24 (Table 2), 701 reports (27.4%) involved routine testing deviations or unexpected events (Table 12). The number of these reports increased 15.5% compared to FY23, which was an increase of 94 reports. Compared to FY23, there were 50 more reports involving compatibility testing and 15 more reports involving antigen typing submitted in FY24.

Table 12 - Most Frequent BPD Reports - Routine Testing from Transfusion Services

Routine Testing (RT)	FY23 (#)	FY23 (% of RT)	FY24 (#)	FY24 (% of RT)
Total RT Reports Received	**607**	**-**	**701**	**-**
Testing performed, interpreted, or documented incorrectly; not performed; incompletely performed; or not documented	***553***	***91.1%***	***647***	***92.3%***
Compatibility	153	25.2%	203	29.0%
Antibody screening or identification	144	23.7%	135	19.3%
Antigen typing	119	19.6%	134	19.1%
ABO and/or Rh typing	98	16.1%	103	14.7%
Sample (used for testing) identification	***54***	***8.9%***	***54***	***7.7%***
Sample used for testing was incorrectly or incompletely labeled	34	5.6%	37	5.3%
Unsuitable sample used for testing	11	1.8%	12	1.7%
Incorrect sample tested	8	1.3%	4	0.6%

Of the 2,173 reports submitted by transfusion services in FY24 (Table 2), 394 reports (15.4%) involved labeling deviations or unexpected events (Table 13). The number of these reports increased 9.1% compared to FY23, which was an increase of 33 reports.

Table 13 - Most Frequent BPD Reports - Labeling from Transfusion Services

Labeling (LA)	FY23 (#)	FY23 (% of LA)	FY24 (#)	FY24 (% of LA)
Total LA Reports Received	**361**	**-**	**394**	**-**
Crossmatch tag, tie tag or transfusion record incorrect or missing information	***266***	***73.7%***	***297***	***75.4%***
Recipient identification incorrect or missing	108	29.9%	100	25.4%
Crossmatch tag, tie tag, or transfusion record missing or attached to incorrect unit	49	13.6%	47	11.9%
Compatibility information incorrect or missing	23	6.4%	34	8.6%
Antigen incorrect or missing	16	4.4%	24	6.1%
Combination of incorrect or missing information	10	2.8%	17	4.3%
Expiration date or time extended or missing	5	1.4%	17	4.3%
Product volume incorrect or missing	16	4.4%	16	4.1%
Product type or code incorrect or missing	10	2.8%	13	3.3%
Labels applied to blood unit incorrect or missing information	***93***	***25.8%***	***95***	***24.1%***
Expiration date or time extended or missing	45	12.5%	39	9.9%
Combination of incorrect or missing information	16	4.4%	21	5.3%
Product type or code incorrect or missing	16	4.4%	10	2.5%
Donor/unit number incorrect or missing	1	0.3%	9	2.3%

4. Most Frequent BPD Reports Submitted by Source Plasma Establishments

Of the 5,365 reports submitted by Source Plasma establishments in FY24 (Table 2), 4,824 reports (89.9%) involved quality control and distribution deviations or unexpected events (Table 14)**.** The number of these reports increased 10.3% compared to FY23, which was an increase of 452 reports. The number of reports related to a donor subsequently testing positive for HBV increased 39.2% compared to FY23. The number of reports related to a donor subsequently testing positive for HCV or HIV decreased 22.9% and 8.3% respectively, compared to FY23.

Table 14 - Most Frequent BPD Reports - Quality Control & Distribution from Source Plasma Establishments

QC & Distribution (QC)	FY23 (#)	FY23 (% of QC)	FY24 (#)	FY24 (% of QC)
Total QC Reports Received	**4,372**	**-**	**4,824**	**-**
Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease	***4,124***	***94.3%***	***4,469***	***92.6%***
HBV	1,884	43.1%	2,622	54.4%
HCV	1,453	33.2%	1,120	23.2%
HIV	783	17.9%	718	14.9%
Distribution of product that did not meet specifications	***235***	***5.4%***	***338***	***7.0%***
Product identified as unsuitable due to a collection deviation or unexpected event	97	2.2%	97	2.0%
Product identified as unsuitable due to a donor screening deviation or unexpected event	71	1.6%	72	1.5%
Product identified as unsuitable due to a transfusion-transmitted infection testing deviation or unexpected event	42	1.0%	70	1.5%
Missing or positive Syphilis testing	26	0.6%	64	1.3%
Failure to quarantine unit due to medical history	***11***	***0.3%***	***11***	***0.2%***

Of the 5,365 reports submitted by Source Plasma establishments in FY24 (Table 2), 459 reports (8.6%) involved donor screening deviations or unexpected events (Table 15). The same number of reports were submitted in FY23 and FY24. There was an increase in reports involving a donor did not meet eligibility criteria (FY23-6; FY24-40) and reports involving a donor providing history which warranted deferral or follow up and was not deferred (FY23-226; FY24-239). There was a decrease in reports involving deferral screening not done or incorrectly performed (FY23-41; FY24-10) and reports involving an incomplete or incorrect donor record (FY23-186; FY24-170).

Table 15 - Most Frequent BPD Reports - Donor Screening from Source Plasma Establishments

Donor Screening (DS)	FY23 (#)	FY23 (% of DS)	FY24 (#)	FY24 (% of DS)
Total DS Reports Received	**459**	**-**	**459**	**-**
Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked	***226***	***49.2%***	***239***	***52.1%***
Unacceptable address	94	20.5%	119	25.9%
Received antibiotics or medication which may adversely affect the product	7	1.5%	27	5.9%
Unreliable donor	27	5.9%	21	4.6%
History of tattoo and/or piercing	25	5.4%	17	3.7%
Donor record incomplete or incorrect	***186***	***40.5%***	***170***	***37.0%***
Donor history questions	134	29.2%	108	23.5%
Donor comprehension	88	19.2%	67	14.6%
Incorrect gender specific question asked or incorrect answer	45	9.8%	40	8.7%
Donor identification	51	11.1%	62	13.5%
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***41***	***8.9%***	***10***	***2.2%***
Donor not previously deferred	34	7.4%	6	1.3%
Donor previously deferred due to history	7	1.5%	4	0.9%
Donor did not meet eligibility criteria	***6***	***1.3%***	***40***	***8.7%***
Medical history interview or physical assessment not performed or inadequate	6	1.3%	38	8.3%

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

Tables 16 through 21 highlight the most frequent reports submitted in FY24 by each type of licensed non-blood manufacturer compared to reports submitted in FY23. 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 88 reports submitted by allergenic manufacturers in FY24 (Table 3), 88% of the reports were related to product specifications (Table 16).

Table 16 - Most Frequent BPD Reports Submitted by Allergenic Manufacturers

Allergenic Manufacturers	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Total Reports	**89**	-	**88**	-
Product Specifications	***81***	***91.0%***	*77*	***87.5%***
Product specification not met; contains precipitate	76	85.4%	76	***86.4%***

Of the 90 reports submitted by plasma derivative manufacturers in FY24 (Table 3), 30% were related to process controls, 26% of the reports were related to quality control and distribution, and 22% were related to product specifications (Table 17).

Table 17 - Most Frequent BPD Reports Submitted by Plasma Derivative Manufacturers

Plasma Derivative Manufacturers	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Total Reports	**63**	-	**90**	-
Process Controls	***15***	***23.8%***	***27***	***30.0%***
Process/Procedure	8	12.7%	19	21.1%
In-process testing/controls not performed, performed incorrectly, or inadequate	2	3.2%	7	7.8%
Media fill failure or media fill performed incorrectly	1	1.6%	6	6.7%
Quality Control and Distribution	***14***	***22.2%***	***23***	***25.6%***
Packing; Broken or cracked vial/syringe	11	17.5%	20	22.2%
Product Specifications	***20***	***31.7%***	***20***	***22.2%***
Stability testing failed	8	12.7%	11	12.2%
Chemical analysis/purity	1	1.6%	3	3.3%
Appearance	4	6.3%	2	2.2%
Potency	1	1.6%	2	2.2%
Component packaged with final product did not meet specifications	8	12.7%	5	5.6%
Broken/cracked vial	8	12.7%	4	4.4%

Of the 66 reports submitted by in-vitro diagnostic manufacturers in FY24 (Table 3), 41% of the reports were related to product specification, 23% were related to quality control and distribution, and 20% were related to labeling (Table 18).

Table 18 - Most Frequent BPD Reports Submitted by In-Vitro Diagnostic Manufacturers

In-Vitro Diagnostic Manufacturers	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Total Reports	**79**	-	**66**	-
Product Specifications	***34***	***43.0%***	***27***	***40.9%***
Product specification not met; Unexpected positive, negative, or weak reactions in testing	27	34.2%	18	27.3%
Quality Control and Distribution	***16***	***20.3%***	***15***	***22.7%***
Shipping and storage	1	1.3%	7	10.6%
Packing	11	13.9%	3	4.5%
Labeling	***12***	***15.2%***	***13***	***19.7%***
Package insert	4	5.1%	3	4.5%
Product label	4	5.1%	3	4.5%
Carton label	0	0.0%	2	3.0%
Lot number	0	0.0%	2	3.0%
Incoming Material	***7***	***8.9%***	***7***	***10.6%***
Incoming container closure did not meet specifications or discovered defective	4	5.1%	6	9.1%

Of the 225 reports submitted by vaccine manufacturers in FY24 (Table 3), 35% of the reports were related to product specifications, 30% were related to quality control and distribution, and 12% were related to incoming material (Table 19).

Table 19 - Most Frequent BPD Reports Submitted by Vaccine Manufacturers

Vaccine Manufacturers	FY23 (#)	FY23 (%)	FY23 (#)	FY24 (%)
Total Reports	**194**	-	**225**	-
Product Specifications	***67***	***34.5%***	***79***	***35.1%***
Product specification not met	47	24.2%	64	28.4%
Appearance	44	22.7%	41	18.2%
Quality Control and Distribution	***54***	***27.8%***	***68***	***30.2%***
Packing; Broken or cracked vial/syringe	53	27.3%	65	28.9%
Incoming Material	***24***	***12.4%***	***28***	***12.4%***
Incoming container, closure or device constituent part did not meet specifications or discovered defective	20	10.3%	28	12.4%

Of the 17 reports submitted by gene therapy manufacturers in FY24 (Table 3), 41% of the reports were related to testing, 18% were related to incoming material, and 18% were related to labeling (Table 20).

Table 20 - Most Frequent BPD Reports Submitted by Gene Therapy Manufacturers

Licensed Gene Therapy Manufacturers	FY22 (#)	FY22 (%)	FY24 (#)	FY24 (%)
Total Reports	***18***	-	**17**	-
Testing *– not performed or not documented*	***9***	***50.0%***	***7***	***41.2%***
Potency	4	22.2%	2	11.8%
Purity	3	16.7%	3	17.6%
Safety	1	5.6%	1	5.9%
Sterility	1	5.6%	1	5.9%
Incoming Material	**2**	**11.1%**	**3**	***17.6%***
Source or raw material does not meet specifications or otherwise found to be unsuitable	2	11.1%	2	11.8%
Incoming container closure did not meet specifications or discovered defective	0	0.0%	1	5.9%
Labeling	***0***	***0.0%***	***3***	***17.6%***
Process Controls	**4**	**22.2%**	**2**	***11.8%***
Product Specifications	***2***	***11.1%***	***1***	***5.9%***
Quality Control & Distribution	***1***	***5.6%***	***1***	***5.9%***

Of the 17 reports submitted by licensed HCT/P manufacturers (351 HCT/Ps) in FY24 (Table 3), 29% of the reports were related to labeling and 24% were related to product specification (Table 21).

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

Licensed HCT/P Manufacturers (351 HCT/Ps)	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Total Reports	**18**	-	**17**	-
Labeling	***6***	***33.3%***	***5***	***29.4%***
Product label; incorrect/illegible; recipient identification	6	33.3%	5	29.4%
Product Specifications	***5***	***27.8%***	***4***	***23.5%***
Product specification not met; contaminated with microorganism	5	27.8%	2	11.8%
Testing	***5***	***27.8%***	***3***	***17.6%***
Safety; performed incorrectly	4	22.2%	1	5.9%
Incoming Material	***1***	***5.6%***	***3***	***17.6%***
Incoming container closure did not meet specifications or discovered defective	1	5.6%	2	11.8%
Source or raw material does not meet specifications or otherwise found to be unsuitable	0	0.0%	1	5.9%
Process Controls	***1***	***5.6%***	***1***	***5.9%***
Quality Control & Distribution	***0***	***0.0%***	***1***	***5.9%***

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

Tables 22 and 23 highlight the most frequent reports submitted in FY24 by each type of 361 HCT/P manufacturer compared to reports submitted in FY23. 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 128 reports submitted by cellular 361 HCT/P manufacturers in FY24 (Table 4), 82% of the reports involved receipt, pre-distribution, shipment, and distribution and 12% involved processing and process controls (Table 22).

Table 22 - Most Frequent HCT/P Deviation Reports Submitted by Cellular 361 HCT/Ps Manufacturers

Cellular 361 HCT/Ps Manufacturers	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Total Reports	**134**	-	**128**	-
Receipt, Pre-Distribution, Shipment & Distribution	***100***	***74.6%***	***105***	***82.0%***
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	96	71.6%	102	79.7%
Processing & Processing Controls	***16***	***11.9%***	***15***	***11.7%***
Processing; HCT/P contaminated, potentially contaminated, or cross-contaminated during processing	11	8.2%	10	7.8%
In-process controls; Not followed	5	3.7%	4	3.1%

Of the 84 reports submitted by tissue 361 HCT/P manufacturers in FY24 (Table 4), 56% of the reports involved donor eligibility and 14% involved receipt, pre-distribution, shipment, and distribution (Table 23). The number of reports involving a donor with a history of sepsis or possible sepsis increased from two in FY23 to 18 in FY24.

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

Tissue 361 HCT/Ps Manufacturers	FY23 (#)	FY23 (%)	FY24 (#)	FY24 (%)
Total Reports	**95**	-	**84**	-
Donor Eligibility	***14***	***14.7%***	***47***	***56.0%***
Ineligible donor accepted; Risk factors for, or clinical evidence of infection due to RCDAD	9	9.5%	38	45.2%
Final autopsy results received post distribution	3	3.2%	7	8.3%
Donor eligibility determination; Not determined by a responsible person	1	1.1%	3	3.6%
Receipt, Pre-Distribution, Shipment & Distribution	***40***	***42.1%***	***12***	***14.3%***
Inappropriate shipping conditions; Packaging	14	14.7%	5	6.0%
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	22	23.2%	4	4.8%
Donor Testing	***16***	***16.8%***	***11***	***13.1%***
Unacceptable specimen tested; Donor incorrectly or not evaluated for plasma dilution	13	13.7%	7	8.3%
Testing not performed or documented, or incorrectly performed when required, for	2	2.1%	2	2.4%
Multiple tests – all testing	1	1.1%	2	2.4%
Processing & Processing Controls	***4***	***4.2%***	***6***	***7.1%***
In-process controls; Not followed	1	1.1%	3	3.6%