

M E M O R A N D U M

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE: OCT 28 1999

FROM: Sharon O'Callaghan, ^{ASO}CSO,
Division of Inspections and Surveillance (HFM-650)

SUBJECT: Error and Accident Reports - Summary for Fourth Quarter FY99

TO: Director, Division of Inspections and Surveillance (HFM-650) 

Between July 1, 1999 and September 30, 1999, the Division of Inspections and Surveillance received 1,748 error and accident reports from the American Red Cross (ARC), 1,560 error and accident reports from non-ARC licensed blood establishments, 18 error and accident reports from unlicensed registered blood establishments, 596 error and accident reports from plasma centers, 7 reports from transfusion services, 4 reports from an in-vitro diagnostic manufacturers, 11 reports from blood derivative manufacturers, 9 reports from vaccine manufacturers, 3 reports from therapeutic manufacturers, and 2 reports from allergenics manufacturers. A total of 3,958 error and accident reports were received. There were 338 (8.5%) reports forwarded to the District Offices for follow-up and evaluation as potential recall situations. Based on the information submitted in the error and accident reports, 148 (3.7%) reports did not appear to meet the threshold for reporting, i.e., products were not made available for distribution or the safety, purity, or potency of a product was not affected.

Between October 1, 1998 and September 30, 1999, the Division of Inspections and Surveillance received a total of 15,532 error and accident reports. There were 1,745 (11.2%) reports forwarded to the District Offices for follow-up and evaluation as potential recall situations. Based on the information submitted in the error and accident reports, 706 (4.5%) reports did not appear to meet the threshold for reporting, i.e., products were not made available for distribution or the safety, purity, or potency of a product was not affected.

Attached are tables and charts that identify the types of reportable and non-reportable errors and accidents submitted. Examples of errors and accidents in the top three categories are provided. A table and graphs representing reportable errors and accidents are also provided that illustrate the distribution of the reporting time, i.e., time from the date the error or accident was discovered to the date CBER received the report.

Attachments

Attachments

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All Reporting Establishments
- 2 - Tables - Types of Errors/Accidents
Blood and Plasma Establishments
Total Reports, Potential Recalls
- 3 - Tables - Types of Errors/Accidents
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Plasma Centers
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All Licensed Blood Establishments

**FOURTH QUARTER - FY99
ALL REPORTING ESTABLISHMENTS**

	TOTAL REPORTS RECEIVED		POTENTIAL RECALLS	
	FOURTH QUARTER	YEAR-TO-DATE	FOURTH QUARTER	YEAR-TO-DATE
AMERICAN RED CROSS	1748	6616	141	480
NON-ARC LICENSED BLOOD BANKS	1560	6664	165	1081
UNLICENSED BLOOD BANKS	18	127	2	17
TRANSFUSION SERVICES	7	30	1	1
PLASMA CENTERS	596	1997	26	145
BLOOD DERIVATIVE MANUFACTURER	11	40	1	7
IN-VITRO DIAGNOSTIC MANUFACTURER	4	17	1	5
VACCINE MANUFACTURER	9	16	0	1
ALLERGENICS MANUFACTURER	2	12	0	4
THERAPEUTIC MANUFACTURER	3	13	1	4
TOTAL	3958		338	
TOTAL - YEAR-TO-DATE 10/1/98 - 9/30/99		15532		1745

The following tables and pie charts show the type of errors and accidents reported:

**FOURTH QUARTER - FY99
BLOOD AND PLASMA ESTABLISHMENTS**

TOTAL ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
ROUTINE TESTING	22	36	1	3	0	62	1.6%
VIRAL TESTING	12	15	0	0	2	29	0.7%
COLLECTION	21	12	0	0	0	33	0.8%
COMPONENT PREPARATION	13	28	1	0	0	42	1.1%
LABELING	134	134	8	3	1	280	7.1%
DONOR SCREENING	65	94	2	0	36	197	5.0%
DONOR DEFERRAL	5	11	0	0	1	17	0.4%
POST DONATION INFO	1315	1052	0	0	538	2905	73.9%
STORAGE/DISTRIBUTION	123	151	6	1	12	293	7.5%
MISCELLANEOUS	38	27	0	0	6	71	1.8%
TOTAL	1748	1560	18	7	596	3929	100%

POTENTIAL RECALLS

TYPE OF ERROR/ACCIDENT	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
ROUTINE TESTING	0	2	0	0	0	2	0.6%
VIRAL TESTING	3	11	0	0	0	14	4.2%
COLLECTION	10	2	0	0	0	12	3.6%
COMPONENT PREPARATION	8	18	0	0	0	26	7.8%
LABELING	21	24	0	1	0	46	13.7%
DONOR SCREENING	47	63	2	0	15	127	37.9%
DONOR DEFERRAL	3	9	0	0	1	13	3.9%
POST DONATION INFO	27	5	0	0	4	36	10.7%
STORAGE/DISTRIBUTION	22	31	0	0	6	59	17.6%
MISCELLANEOUS	0	0	0	0	0	0	0.0%
TOTAL	141	165	2	1	26	335	100%

FOURTH QUARTER - FY99
NON-BLOOD MAUFACTURERS

TYPE OF ERROR/ACCIDENT	DERIVATITVE		IN-VITRO DIAGNOSTIC		ALLERGENIC		THERAPUETIC		VACCINE		TOTAL REPORTS		POTENTIAL RECALL	
	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL				
REAGENT PERFORMANCE	0	0	0	0	0	0	0	0	0	0	0	0.0%	0	0.0%
STERILITY COMPROMISED	1	0	1	1	0	0	0	0	0	0	2	6.9%	1	33.3%
LABELING	0	0	2	0	0	0	0	0	0	0	2	6.9%	0	0.0%
STORAGE/DISTRIBUTION	4	0	0	0	0	0	0	0	0	0	4	13.8%	0	0.0%
MISCELLANEOUS	4	1	1	0	2	0	3	1	9	0	19	65.5%	2	66.7%
NOT REPORTABLE	2	0	0	0	0	0	0	0	0	0	2	6.9%	0	0.0%
TOTAL	11	1	4	1	2	0	3	1	9	0	29	100%	3	100%

YEAR-TO-DATE - FY99
NON-BLOOD MAUFACTURERS

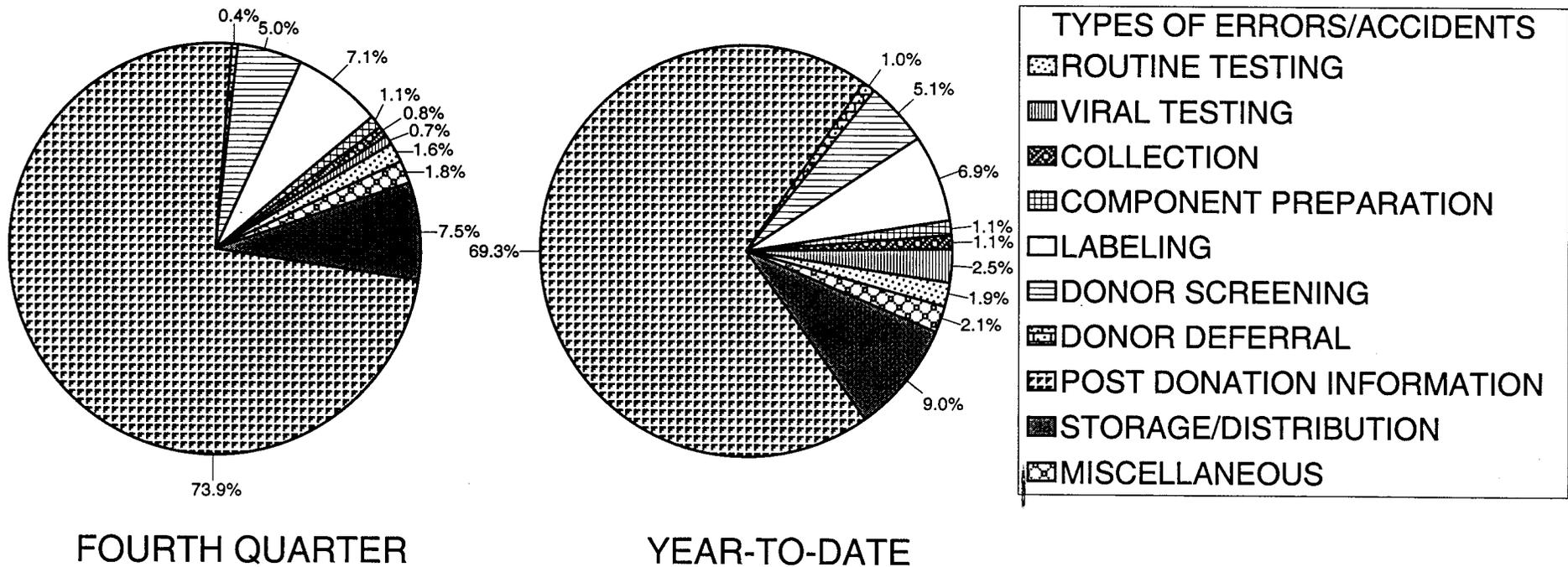
TYPE OF ERROR/ACCIDENT	DERIVATITVE		IN-VITRO DIAGNOSTIC		ALLERGENIC		THERAPUETIC		VACCINE		TOTAL REPORTS		POTENTIAL RECALL	
	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL				
REAGENT PERFORMANCE	0	0	1	1	0	0	0	0	0	0	1	1.0%	1	4.8%
STERILITY COMPROMISED	4	0	3	2	1	0	3	3	1	0	12	12.2%	5	23.8%
LABELING	2	1	9	2	6	4	1	0	0	0	18	18.4%	7	33.3%
STORAGE/DISTRIBUTION	6	0	1	0	1	0	1	0	1	0	10	10.2%	0	0.0%
MISCELLANEOUS	25	6	2	0	4	0	8	1	13	1	52	53.1%	8	38.1%
NOT REPORTABLE	3	0	1	0	0	0	0	0	1	0	5	5.1%	0	0.0%
TOTAL	40	7	17	5	12	4	13	4	16	1	98	100%	21	100%

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

TOTAL REPORTS

FY99



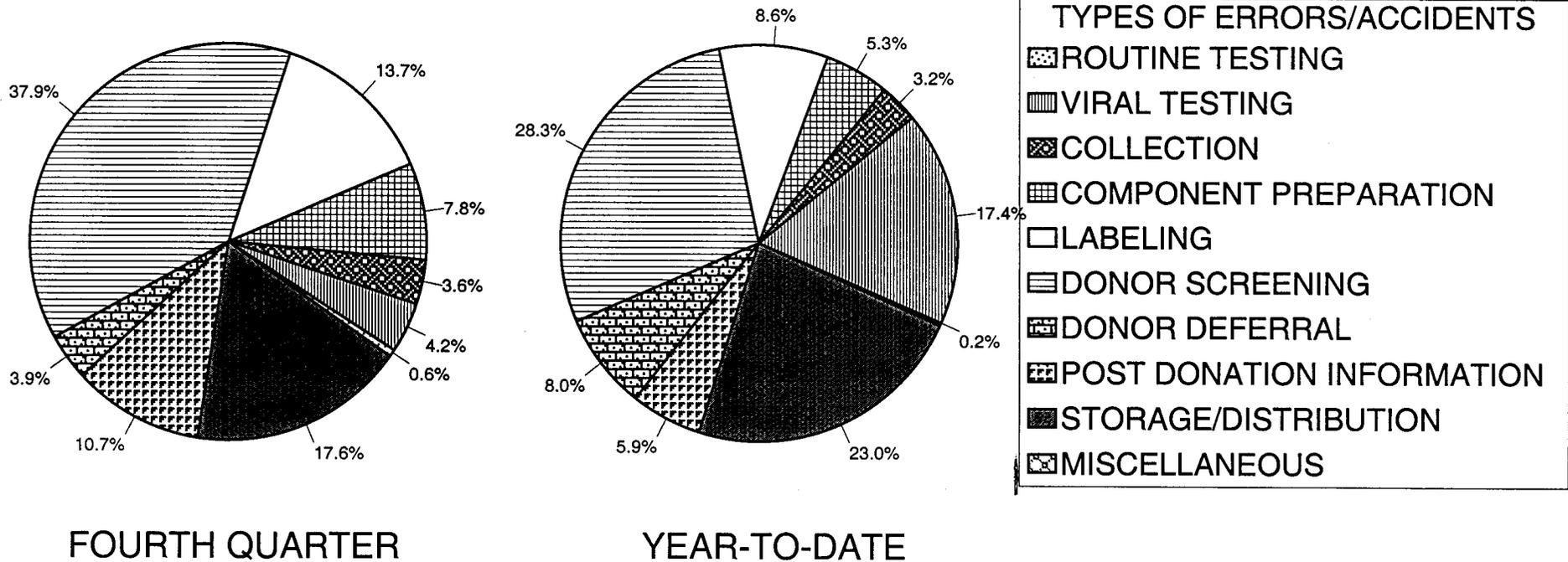
REPORTS RECEIVED FOURTH QUARTER (7/1/99 - 9/30/99) = 3929
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 9/30/99) = 15,434

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

POTENTIAL RECALLS

FY99

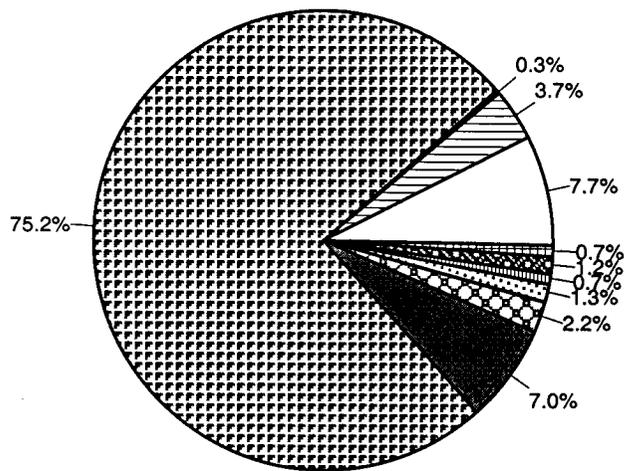


REPORTS RECEIVED FOURTH QUARTER (7/1/99 - 9/30/99) = 335
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 9/30/99) = 1724

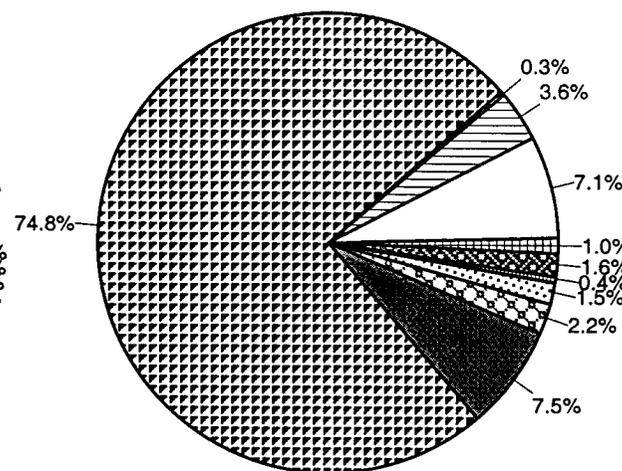
ERROR AND ACCIDENT REPORTS

AMERICAN RED CROSS

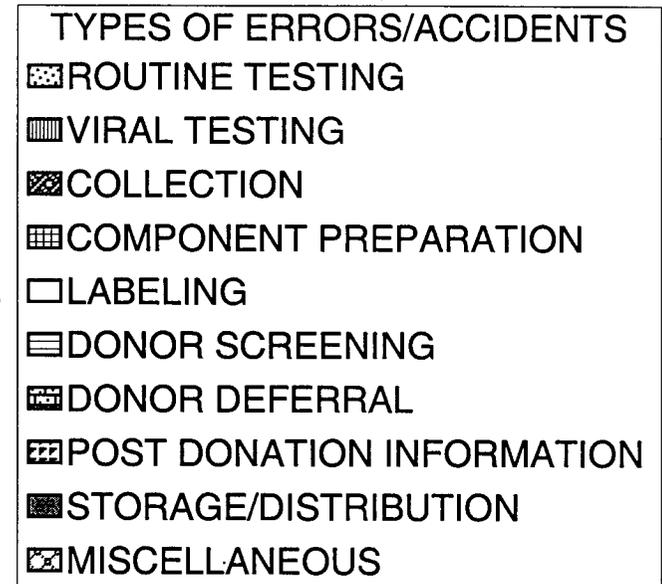
FY99



FOURTH QUARTER



YEAR-TO-DATE

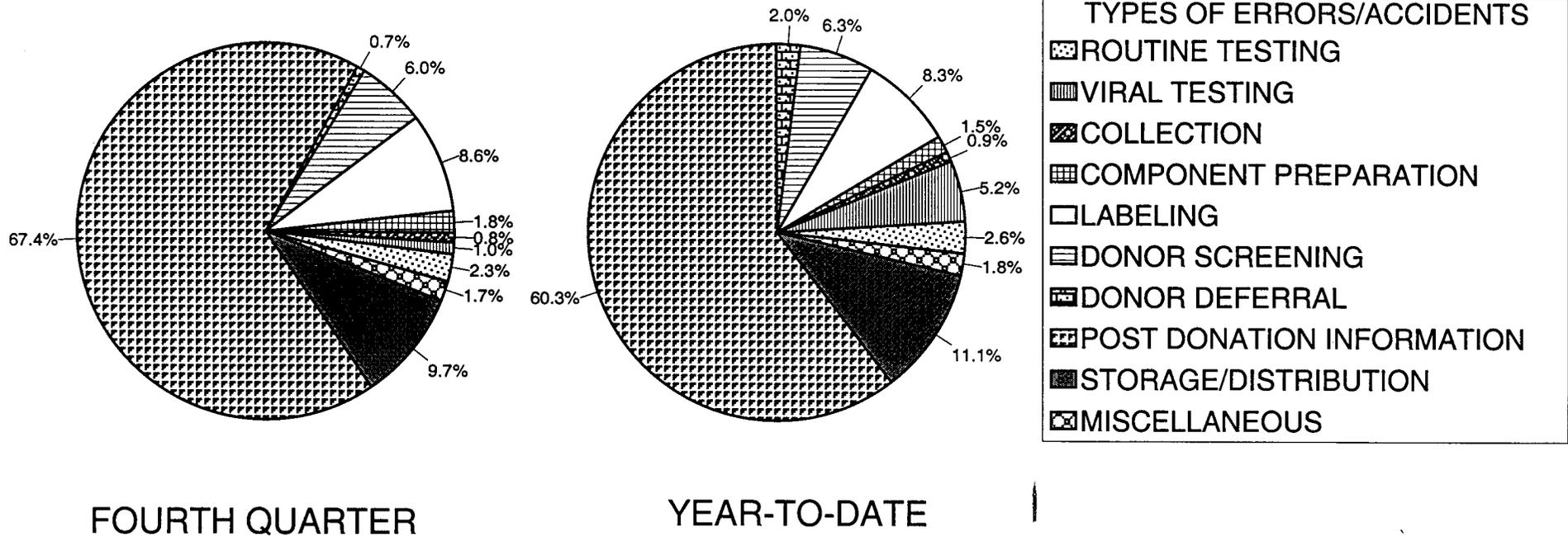


REPORTS RECEIVED FOURTH QUARTER (7/1/99 - 9/30/99) = 1748
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 9/30/99) = 6616

ERROR AND ACCIDENT REPORTS

NON-ARC LICENSED BLOOD BANKS

FY99

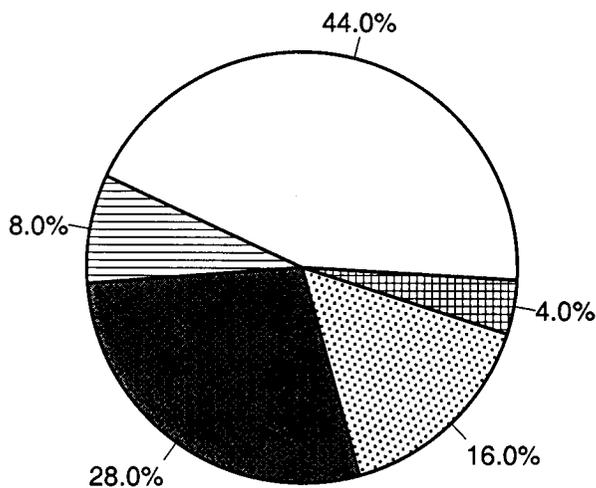


REPORTS RECEIVED FOURTH QUARTER (7/1/99 - 9/30/99) = 1560
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 9/30/99) = 6664

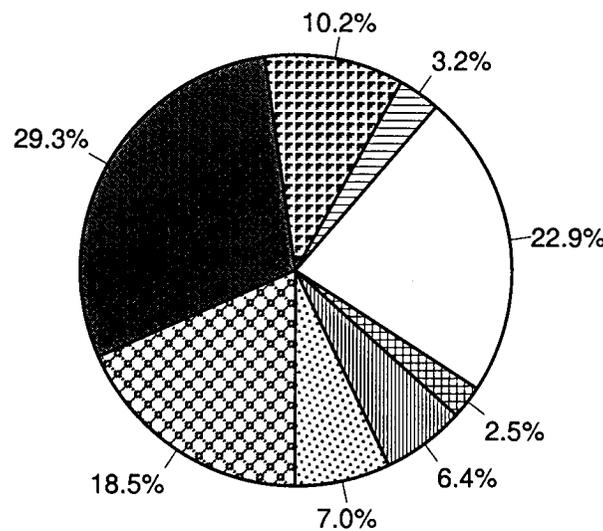
ERROR AND ACCIDENT REPORTS

UNLICENSED BLOOD BANKS

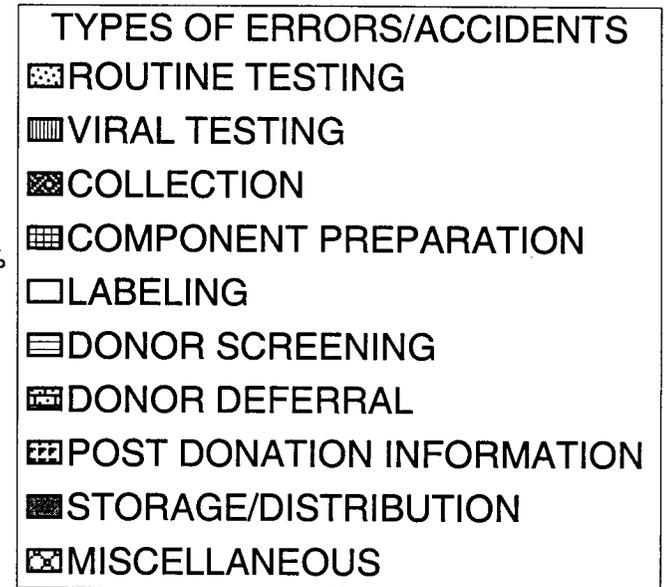
FY99



FOURTH QUARTER



YEAR-TO-DATE

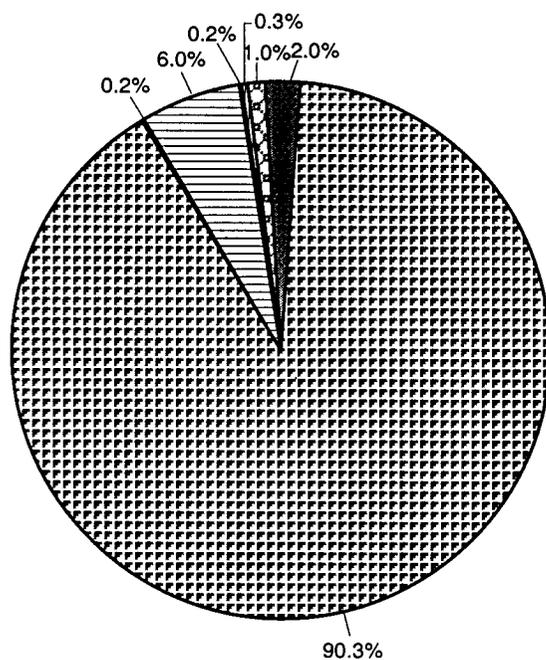


REPORTS RECEIVED FOURTH QUARTER (7/1/99 - 9/30/99) = 25 (7 REPORTS - TRANSFUSION SERVICES)
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 9/30/99) = 157 (30 REPORTS - TRANSFUSION SERVICES)

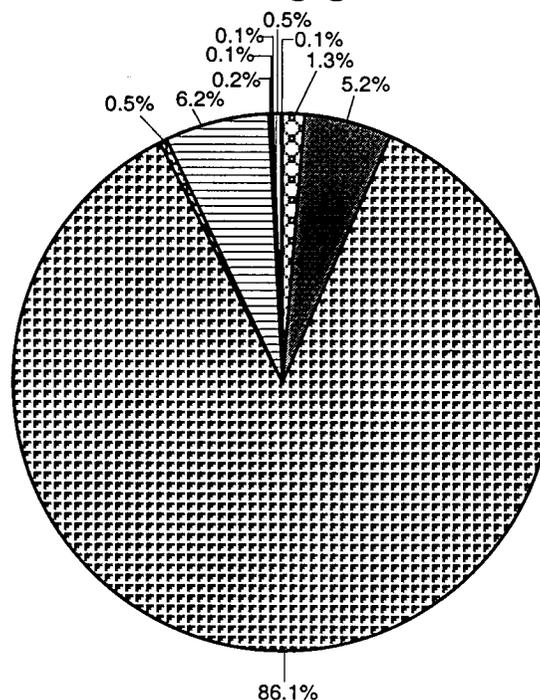
ERROR AND ACCIDENT REPORTS

PLASMA CENTERS

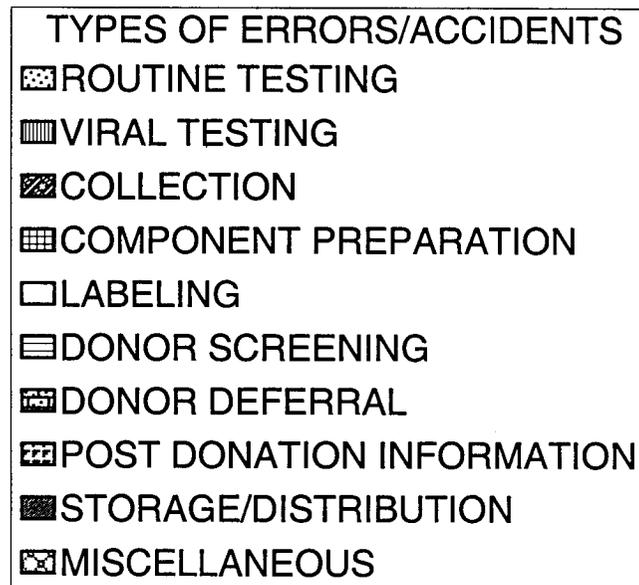
FY99



FOURTH QUARTER



YEAR-TO-DATE

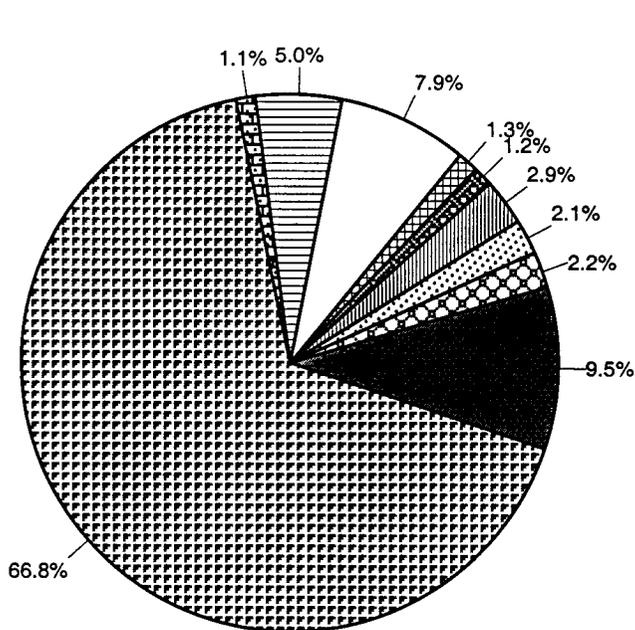


REPORTS RECEIVED FOURTH QUARTER (7/1/99 - 9/30/99) = 596
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 9/30/99) = 1997

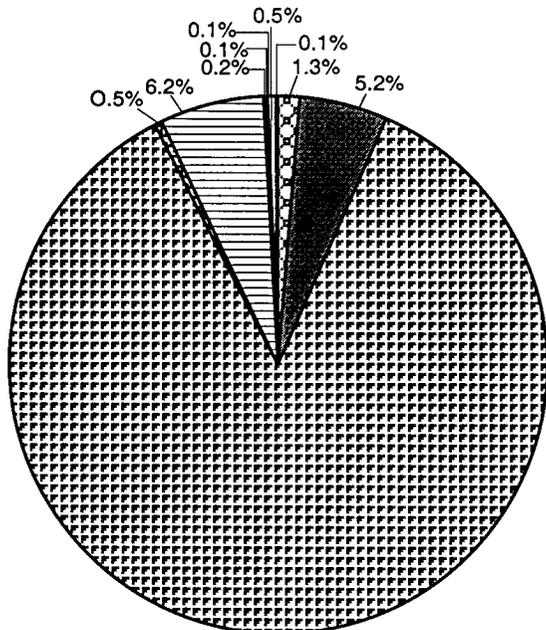
ERROR AND ACCIDENT REPORTS

BLOOD BANKS VERSUS PLASMA CENTERS

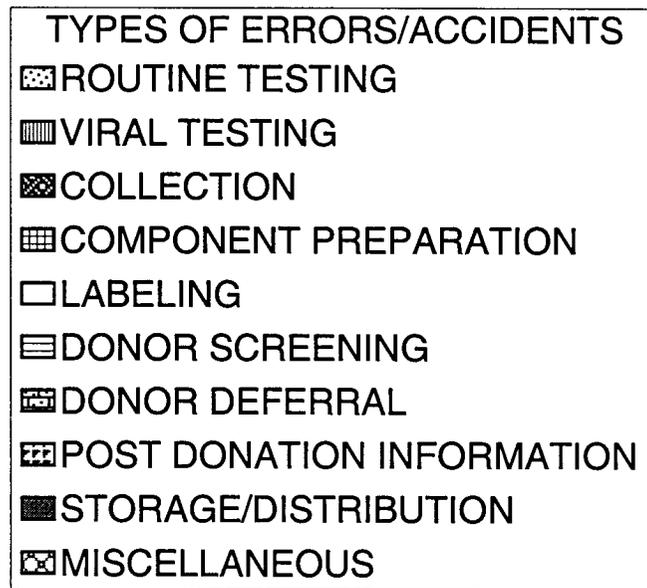
FY99 YEAR-TO-DATE



BLOOD BANKS



YEAR-TO-DATE

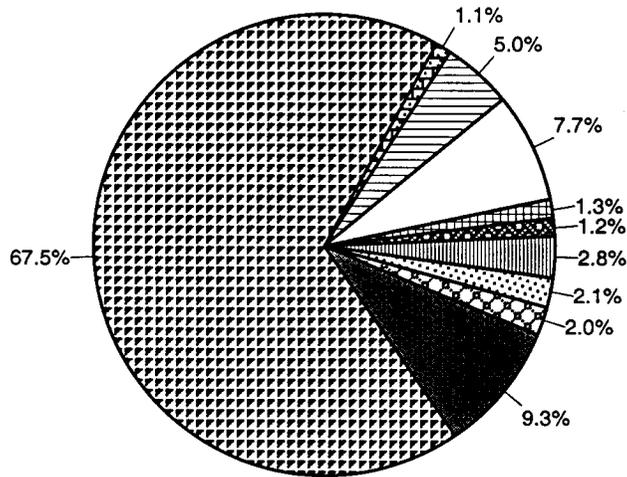


REPORTS RECEIVED 10/1/98 - 9/30/99
 BLOOD BANKS = 13,437
 PLASMA CENTERS = 1997

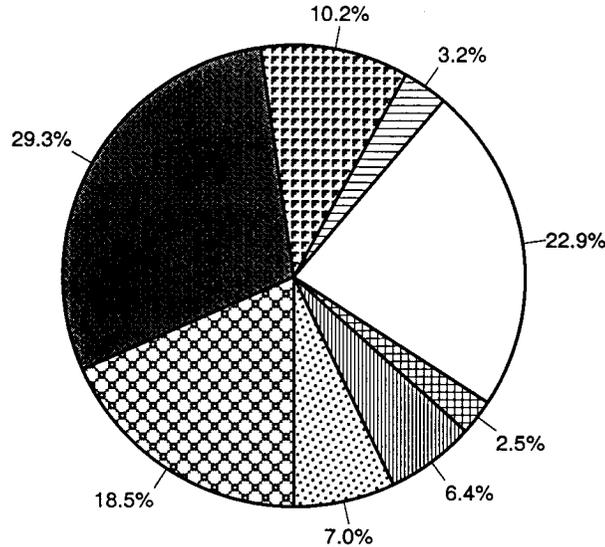
ERROR AND ACCIDENT REPORTS

BLOOD BANKS VERSUS PLASMA CENTERS

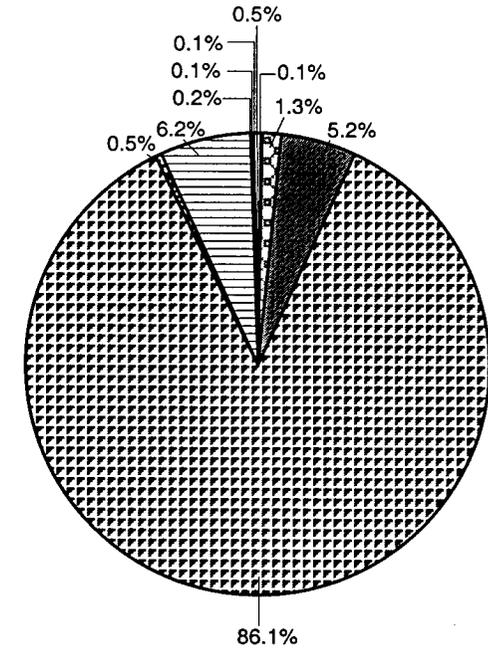
FY99 YEAR-TO-DATE



LICENSED BLOOD BANKS



UNLICENSED BLOOD BANKS



PLASMA CENTERS

TYPES OF ERRORS/ACCIDENTS

- ROUTINE TESTING
- COMPONENT PREPARATION
- DONOR DEFERRAL
- MISCELLANEOUS
- VIRAL TESTING
- LABELING
- POST DONATION INFORMATION
- COLLECTION
- DONOR SCREENING
- STORAGE/DISTRIBUTION

REPORTS RECEIVED 10/1/98 - 9/30/99
 LICENSED BLOOD BANKS = 13,280
 UNLICENSED BLOOD BANKS = 157
 PLASMA CENTERS = 1997

FOURTH QUARTER - FY99
BLOOD AND PLASMA ESTABLISHMENTS

TYPE OF ERROR/ACCIDENT	NON-REPORTABLE	REPORTABLE	TOTAL	%NON-REPORTABLE
ROUTINE TESTING	5	57	62	8.1%
VIRAL TESTING	0	29	29	0.0%
COLLECTION	8	25	33	24.2%
COMPONENT PREPARATION	1	41	42	2.4%
LABELING	30	250	280	10.7%
DONOR SCREENING	8	189	197	4.1%
DONOR DEFERRAL	3	14	17	17.6%
POST DONATION INFORMATION	8	2897	2905	0.3%
STORAGE/DISTRIBUTION	16	277	293	5.5%
MISCELLANEOUS	67	4	71	94.4%
TOTAL	146	3783	3929	3.7%

%NON-REPORTABLE = Non-Reportable/Total for each category

YEAR-TO-DATE - FY99
BLOOD AND PLASMA ESTABLISHMENTS

TYPE OF ERROR/ACCIDENT	NON-REPORTABLE	REPORTABLE	TOTAL	%NON-REPORTABLE
ROUTINE TESTING	7	280	287	2.4%
VIRAL TESTING	10	382	392	2.6%
COLLECTION	37	126	163	22.7%
COMPONENT PREPARATION	3	170	173	1.7%
LABELING	151	912	1063	14.2%
DONOR SCREENING	57	733	790	7.2%
DONOR DEFERRAL	8	153	161	5.0%
POST DONATION INFORMATION	61	10639	10699	0.6%
STORAGE/DISTRIBUTION	66	1319	1383	4.7%
MISCELLANEOUS	301	19	320	94.1%
TOTAL	701	14733	15431	4.5%

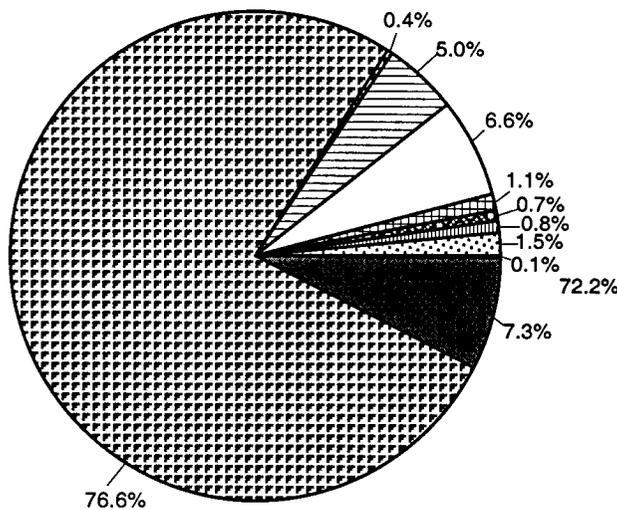
%NON-REPORTABLE = Non-Reportable/Total for each category

ERROR AND ACCIDENT REPORTS

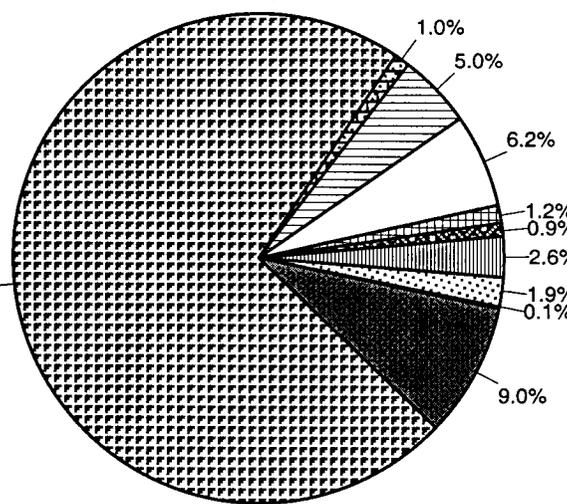
ALL BLOOD AND PLASMA ESTABLISHMENTS

REPORTABLE ERRORS/ACCIDENTS

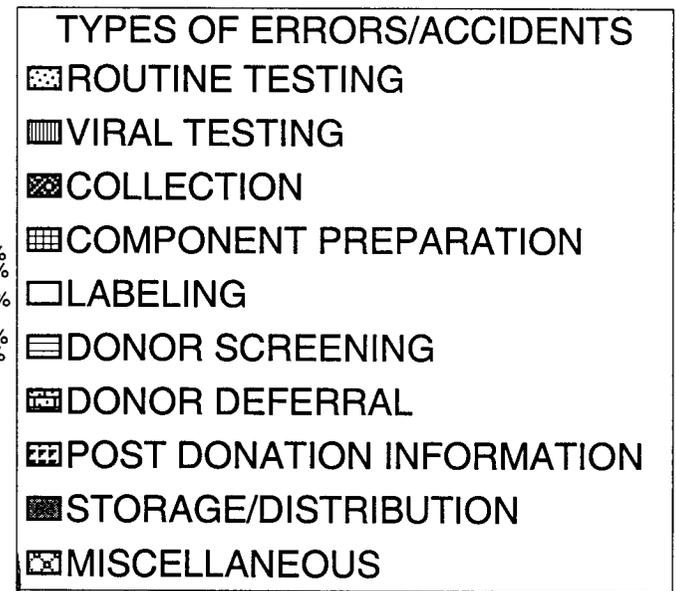
FY99



FOURTH QUARTER



YEAR-TO-DATE



REPORTS RECEIVED FOURTH QUARTER (7/1/99 - 9/30/99) = 3783

REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 9/30/99) = 14,733

FY99 YEAR-TO-DATE

REPORTABLE ERRORS/ACCIDENTS – 14,733(95.5% of total reports)

Top Three Categories of Errors/Accidents:

Post Donation Information – 10,639 (72.2% of reportables)

**Examples:*

Information provided post donation:

- Donor received tattoo, earpiercing, accidental needlestick, or transfusion
- Donor traveled to a malarial endemic area
- Donor had a history of cancer
- Donor became ill after donation,
not related to hepatitis, HIV, HTLV-I, sexually transmitted diseases or cold/flu symptoms

Storage/Distribution – 1319 (8.9% of reportables)

**Examples:*

- Release of product that contained clots or would not flow through a filter
- Product was shipped or stored at incorrect temperature
- Failure to quarantine a unit that was designated to be quarantined due to incorrect, incomplete, or positive testing
- Failure to quarantine a unit that was designated to be quarantined due to testing not performed or documented

Labeling – 912 (6.2% of reportables)

**Examples:*

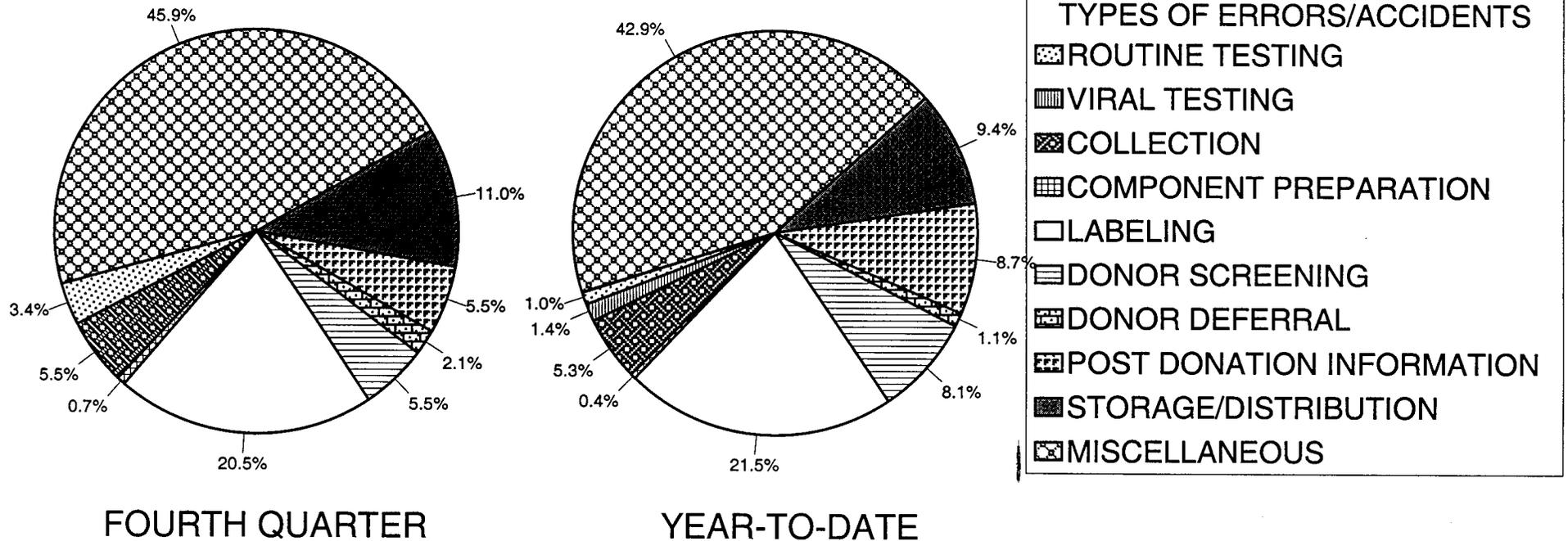
- Additional information on autologous unit incorrect or missing, e.g., name, social security number, or date of birth
- Product labeled with extended expiration date
- Missing or incorrect donor/unit number
- Incorrect ABO/Rh

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

NON-REPORTABLE ERRORS/ACCIDENTS

FY99



REPORTS RECEIVED FOURTH QUARTER (7/1/99 - 9/30/99) = 146

REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 9/30/99) = 701

FY99 YEAR-TO-DATE

NON-REPORTABLE ERRORS/ACCIDENTS - 701 (4.5% of total reports)

Top Three Categories of Errors/Accidents:

Miscellaneous 301 (42.9% of non-reportables)

**Examples:*

- No products made available for distribution
- Notification/retrieval procedures not followed (e.g., notification not performed within appropriate time)
- Recordkeeping error/accident (manual or computer) - record is incorrect or not reviewed; testing and labeling are acceptable

Labeling - 151 (21.5% of non-reportables)

**Examples:*

- Unit labeled with incorrect weight, volume, collection date, or facility identifiers; unit acceptable
- Unit labeled with a shortened expiration date
- Unit missing label for ABO/Rh, product, or expiration date

Storage and Distribution 66 (9.4% of non-reportables)

**Example:*

- Failure to quarantine unit after receiving information regarding post donation cold or flu symptoms
- Discrepancy between shipping form and shipment
- Irradiated unit requested, unit not irradiated, but labeled appropriately

The following table and graphs show the time periods in which the reports were received by CBER. The evaluation of timeliness is limited to only reports that met the threshold for reporting.

**ERROR AND ACCIDENT REPORTS
FOURTH QUARTER - FY99**

**NUMBER OF DAYS FROM DATE E/A DISCOVERED TO FDA RECEIVED
BLOOD ESTABLISHMENTS**

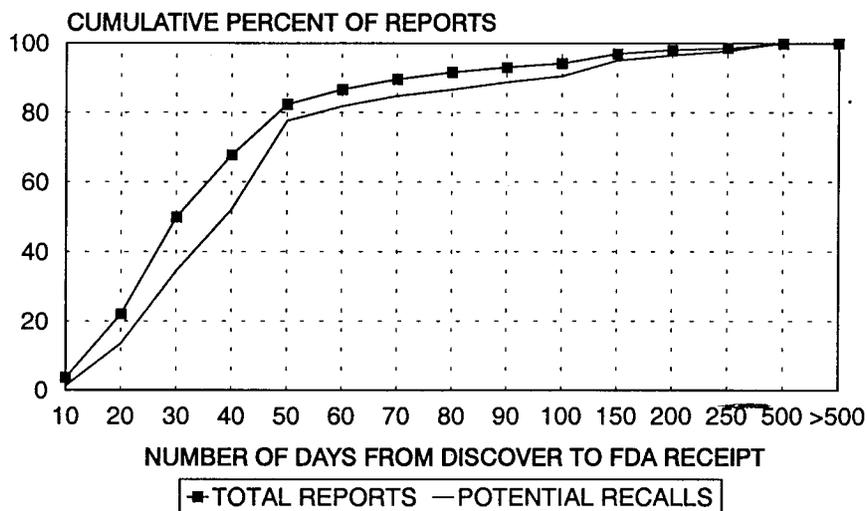
CUMULATIVE PERCENT OF REPORTS	ARC (DAYS)	NON-ARC LICENSED (DAYS)	UNLICENSED (DAYS)	PLASMA (DAYS)	TOTAL (DAYS)
10%	16	14	6	13	14
25%	22	21	13	20	21
50%	30	31	27	30	30
75%	40	56	45	52	45
90%	49	102	99	85	73
# REPORTS	1669	1500	23	591	3783
RANGE	2-298	4-601	3-153	3-485	2-601

**ERROR AND ACCIDENT REPORTS
RECEIVED 10/1/98 - 9/30/99**

**NUMBER OF DAYS FROM DATE E/A DISCOVERED TO FDA RECEIVED
BLOOD ESTABLISHMENTS**

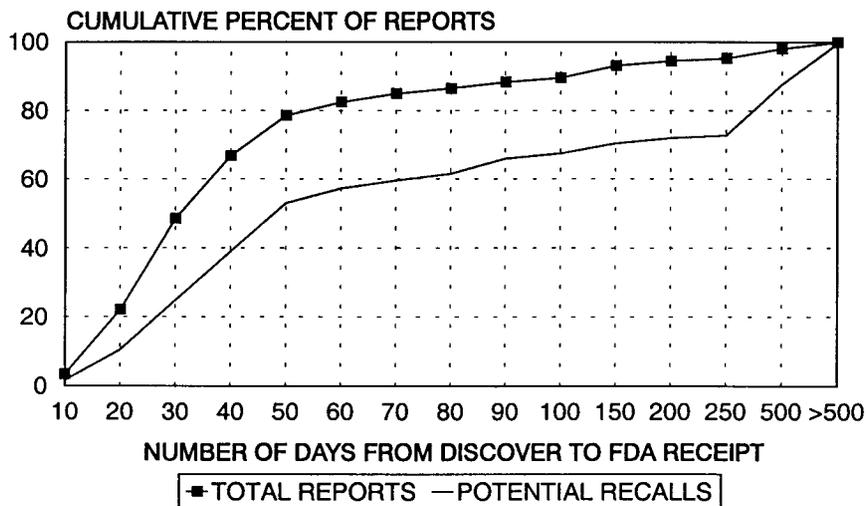
CUMULATIVE PERCENT OF REPORTS	ARC (DAYS)	NON-ARC LICENSED (DAYS)	UNLICENSED (DAYS)	PLASMA (DAYS)	TOTAL (DAYS)
10%	16	15	7	12	14
25%	21	22	14	17	21
50%	29	34	31	28	331
75%	39	79	79	54	47
90%	47	214	197	118	104
# REPORTS	6246	6396	122	1965	14733
RANGE	1-383	3-2385	1-831	3-1221	1-2385

ERROR AND ACCIDENT REPORTS REPORTING TIME ALL REPORTING BLOOD ESTABLISHMENTS FOURTH QUARTER FY99



TOTAL REPORTS = 3783
POTENTIAL RECALLS = 334

ERROR AND ACCIDENT REPORTS REPORTING TIME ALL REPORTING BLOOD ESTABLISHMENTS YEAR -TO-DATE FY99

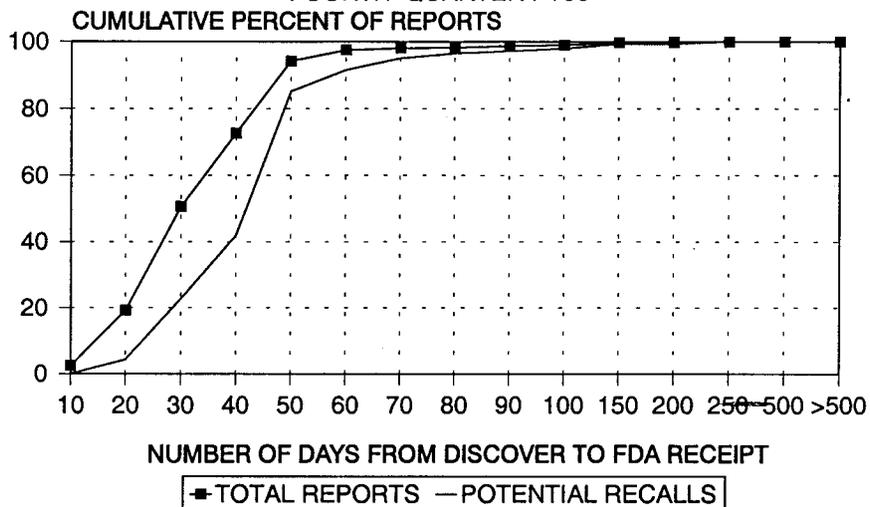


TOTAL REPORTS = 14,733
POTENTIAL RECALLS = 1724

ERROR AND ACCIDENT REPORTS

REPORTING TIME AMERICAN RED CROSS

FOURTH QUARTER FY99

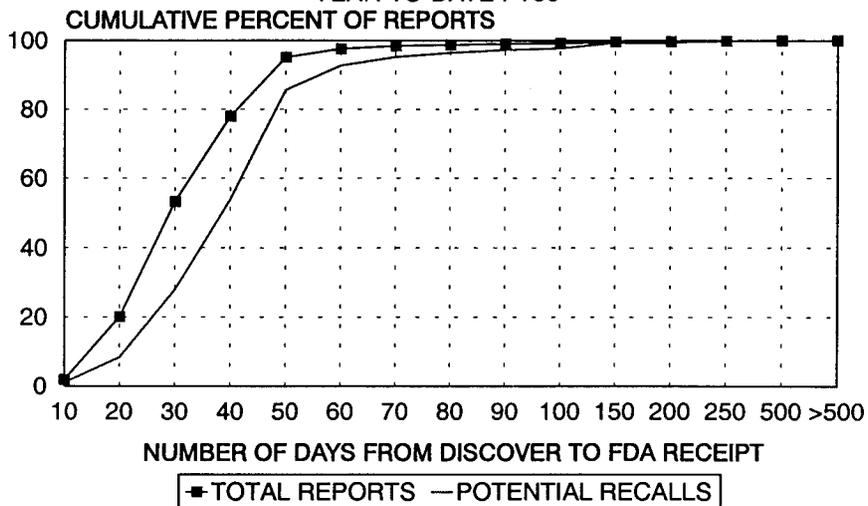


TOTAL REPORTS = 1669
POTENTIAL RECALLS = 141

ERROR AND ACCIDENT REPORTS

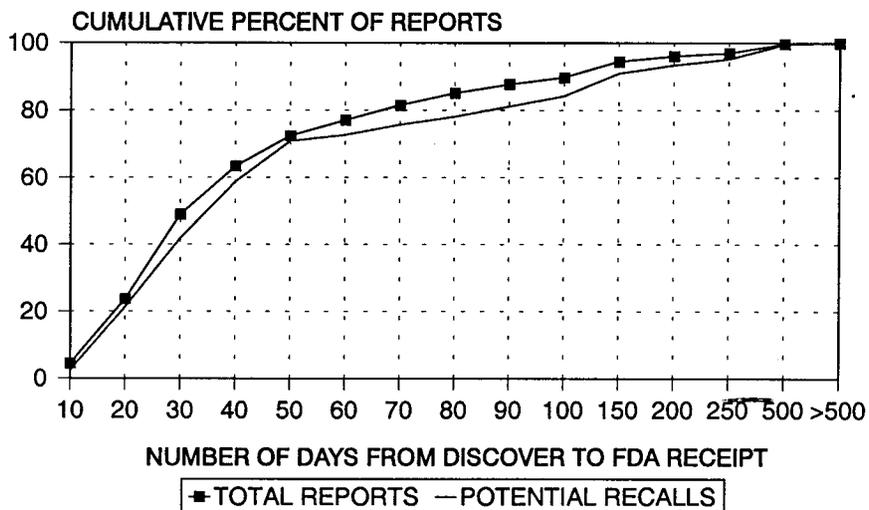
REPORTING TIME AMERICAN RED CROSS

YEAR-TO-DATE FY99



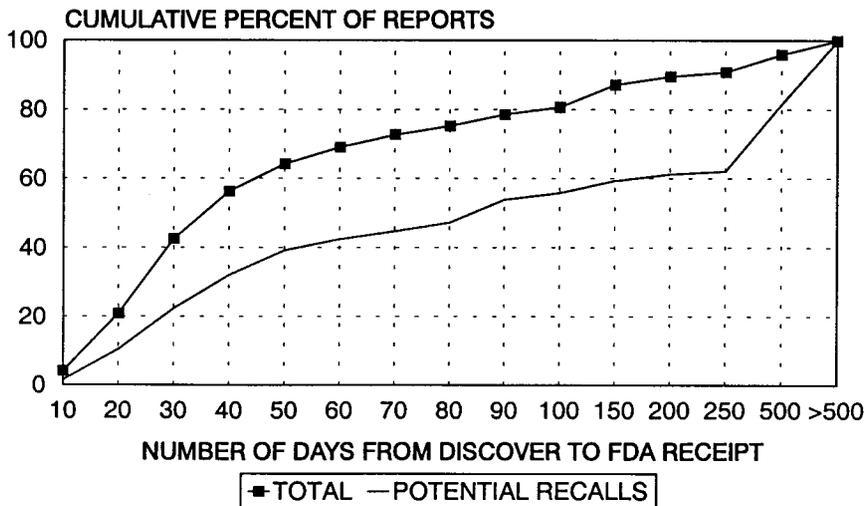
TOTAL REPORTS = 6246
POTENTIAL RECALLS = 480

ERROR AND ACCIDENT REPORTS REPORTING TIME NON-ARC LICENSED BLOOD BANKS FOURTH QUARTER FY99



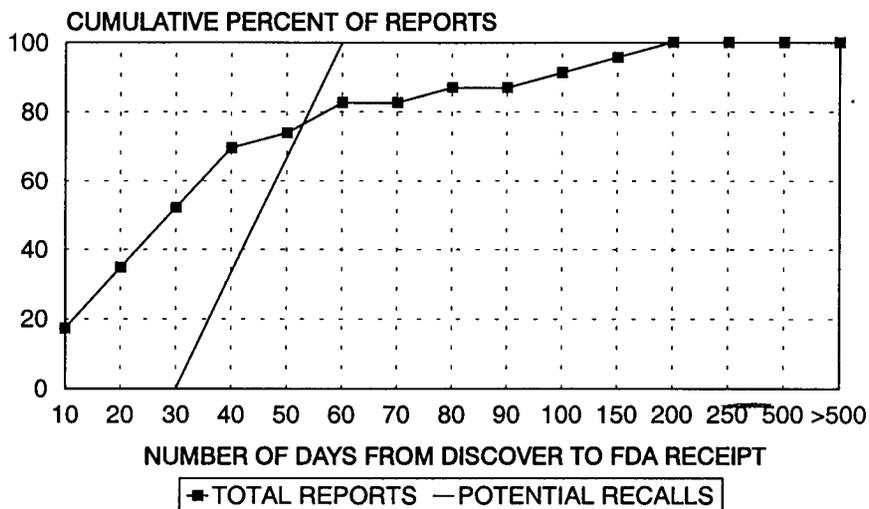
TOTAL REPORTS = 1500
POTENTIAL RECALLS = 165

ERROR AND ACCIDENT REPORTS REPORTING TIME NON-ARC LICENSED BLOOD BANKS YEAR-TO-DATE FY99



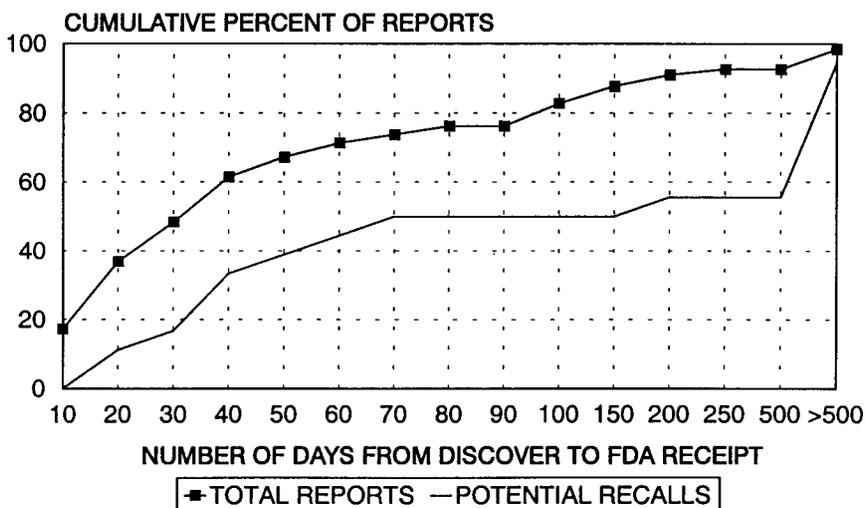
TOTAL REPORTS = 6396
POTENTIAL RECALLS = 1081

ERROR AND ACCIDENT REPORTS REPORTING TIME UNLICENSED BLOOD BANKS FOURTH QUARTER FY99



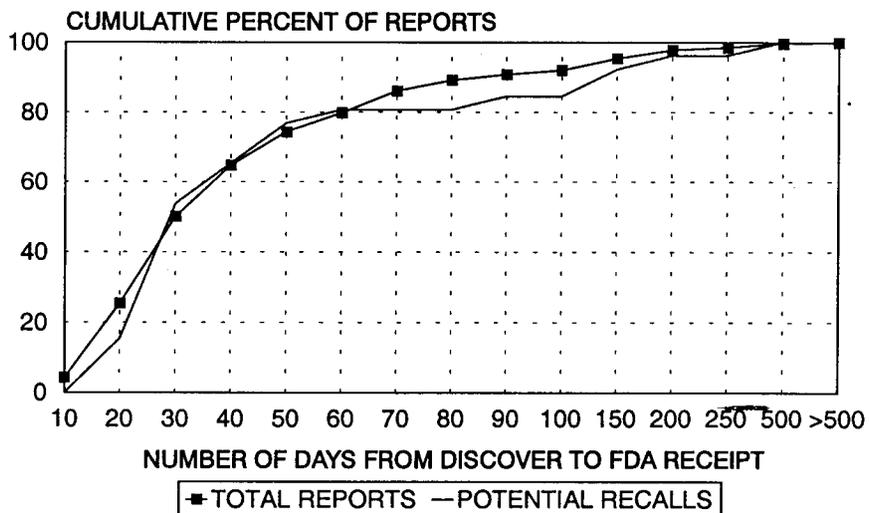
TOTAL REPORTS = 23
POTENTIAL RECALLS = 3

ERROR AND ACCIDENT REPORTS REPORTING TIME UNLICENSED BLOOD BANKS YEAR-TO-DATE FY99



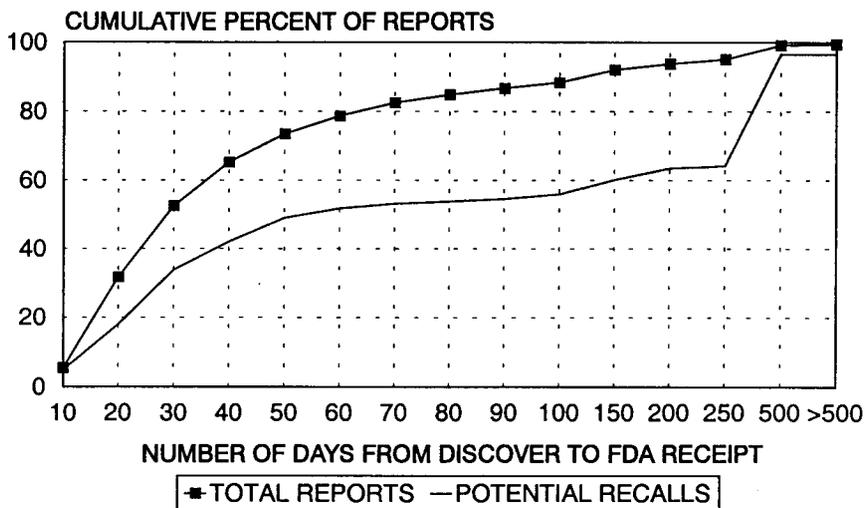
TOTAL REPORTS = 122
POTENTIAL RECALLS = 18

ERROR AND ACCIDENT REPORTS REPORTING TIME PLASMA CENTERS FOURTH QUARTER FY99



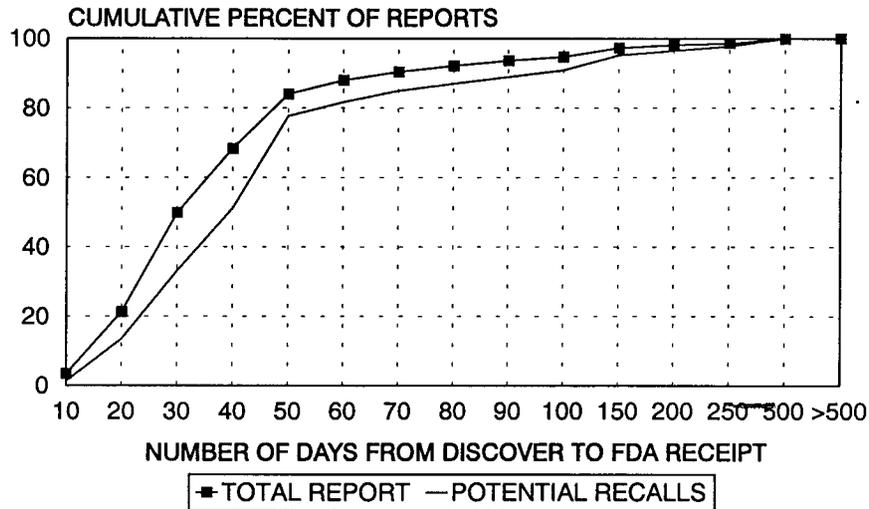
TOTAL REPORTS = 591
POTENTIAL RECALLS = 26

ERROR AND ACCIDENT REPORTS REPORTING TIME PLASMA CENTERS YEAR-TO-DATE FY99



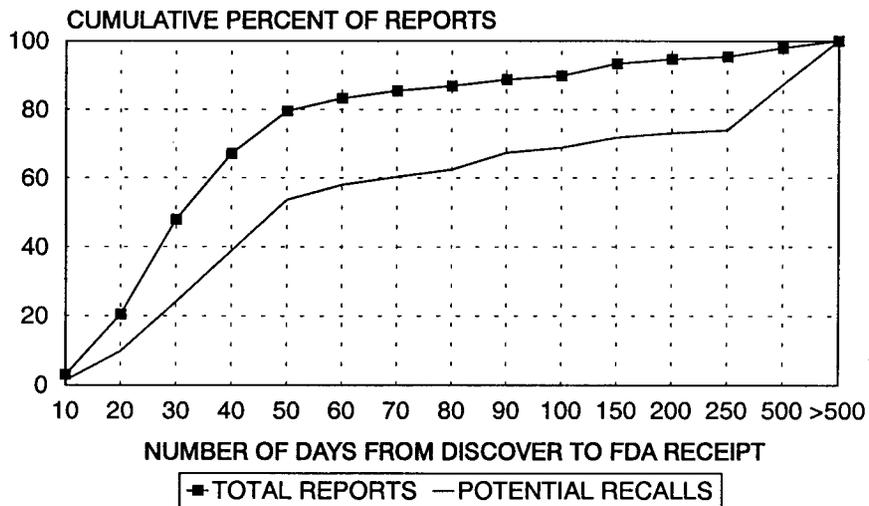
TOTAL REPORTS = 1965
POTENTIAL RECALLS = 145

ERROR AND ACCIDENT REPORTS REPORTING TIME ALL LICENSED BLOOD BANKS FOURTH QUARTER FY99



TOTAL REPORTS = 3169
POTENTIAL RECALLS = 306

ERROR AND ACCIDENT REPORTS REPORTING TIME ALL LICENSED BLOOD BANKS YEAR-TO-DATE FY99



TOTAL REPORTS = 12,642
POTENTIAL RECALLS = 1561