

MEMORANDUM

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

DATE: APR 20 1999

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

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

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

Between January 1, 1999 and March 31, 1999, the Division of Inspections and Surveillance received 1,663 error and accident reports from the American Red Cross (ARC), 1,808 error and accident reports from non-ARC licensed blood establishments, 46 error and accident reports from unlicensed registered blood establishments, 537 error and accident reports from plasma centers, 6 reports from transfusion services, 8 reports from an in-vitro diagnostic manufacturers, 6 reports from blood derivative manufacturers, 3 reports from vaccine manufacturers, 4 reports from therapeutic manufacturers, and 3 reports from allergenics manufacturers. A total of 4,084 error and accident reports were received. There were 615 (15.1%) 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, 196 (4.8%) 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 March 31, 1999, the Division of Inspections and Surveillance received a total of 7,694 error and accident reports. There were 1107 (14.4%) 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, 388 (5.0%) 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

- 1 - Table - Total Error/Accident Reports
All Reporting Establishments
- 2 - Tables - Types of Errors/Accidents
Blood and Plasma Establishments
Total Reports, Potential Recalls
- 3 - Tables - Types of Errors/Accidents
Non-Blood Manufacturers
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Plasma Centers
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All Licensed Blood Establishments

SECOND QUARTER - FY99
ALL REPORTING ESTABLISHMENTS

	TOTAL REPORTS RECEIVED		POTENTIAL RECALLS	
	SECOND QUARTER	YEAR-TO-DATE	SECOND QUARTER	YEAR-TO-DATE
AMERICAN RED CROSS	1663	3298	110	234
NON-ARC LICENSED BLOOD BANKS	1808	3460	429	769
UNLICENSED BLOOD BANKS	46	86	11	13
TRANSFUSION SERVICES	6	10	0	0
PLASMA CENTERS	537	803	61	81
BLOOD DERIVATIVE MANUFACTURER	6	13	0	1
IN-VITRO DIAGNOSTIC MANUFACTURER	8	10	2	4
VACCINE MANUFACTURER	3	3	1	1
ALLERGENICS MANUFACTURER	3	4	0	1
THERAPEUTIC MANUFACTURER	4	7	1	3
TOTAL	4084		615	
TOTAL - YEAR-TO-DATE 10/1/98 - 3/31/99		7694		1107

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

**SECOND 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	39	1	0	2	64	1.6%
VIRAL TESTING	4	194	9	0	3	210	5.2%
COLLECTION	24	15	0	0	0	39	1.0%
COMPONENT PREPARATION	19	24	1	0	1	45	1.1%
LABELING	103	132	10	0	0	245	6.0%
DONOR SCREENING	54	117	3	0	21	195	4.8%
DONOR DEFERRAL	4	75	0	0	4	83	2.0%
POST DONATION INFO	1263	997	4	0	446	2710	66.7%
STORAGE/DISTRIBUTION	123	186	8	5	55	377	9.3%
MISCELLANEOUS	47	29	10	1	5	92	2.3%
TOTAL	1663	1808	46	6	537	4060	100%

POTENTIAL RECALLS

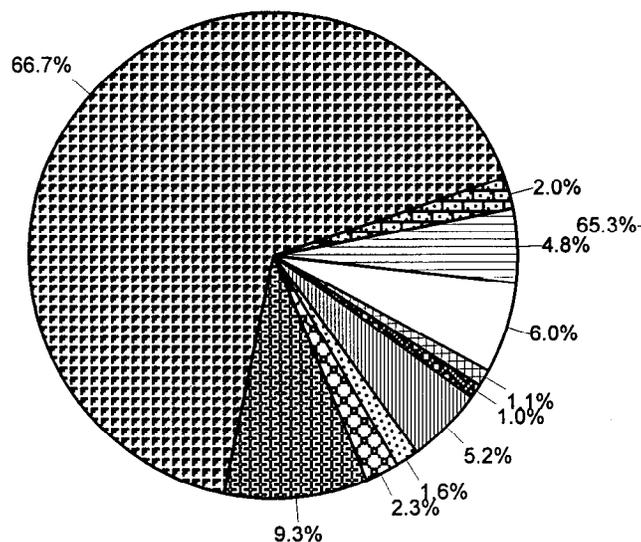
TYPE OF ERROR/ACCIDENT	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
ROUTINE TESTING	0	1	0	0	0	1	0.2%
VIRAL TESTING	0	180	7	0	1	188	30.8%
COLLECTION	7	6	0	0	0	13	2.1%
COMPONENT PREPARATION	10	17	0	0	0	27	4.4%
LABELING	15	25	2	0	0	42	6.9%
DONOR SCREENING	37	70	1	0	10	118	19.3%
DONOR DEFERRAL	3	72	0	0	2	77	12.6%
POST DONATION INFO	12	4	0	0	4	20	3.3%
STORAGE/DISTRIBUTION	26	54	1	0	44	125	20.5%
MISCELLANEOUS	0	0	0	0	0	0	0.0%
TOTAL	110	429	11	0	61	611	100%

ERROR AND ACCIDENT REPORTS

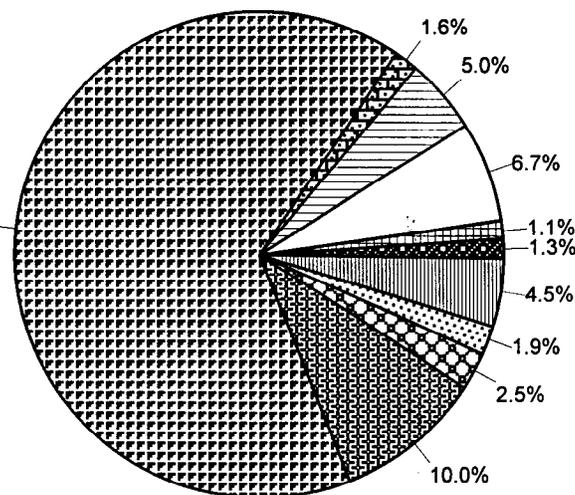
ALL BLOOD AND PLASMA ESTABLISHMENTS

TOTAL REPORTS

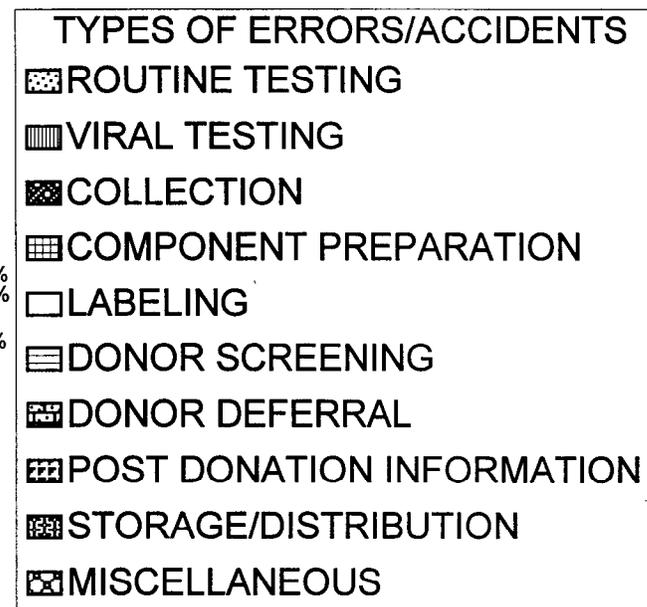
FY99



SECOND QUARTER



YEAR-TO-DATE



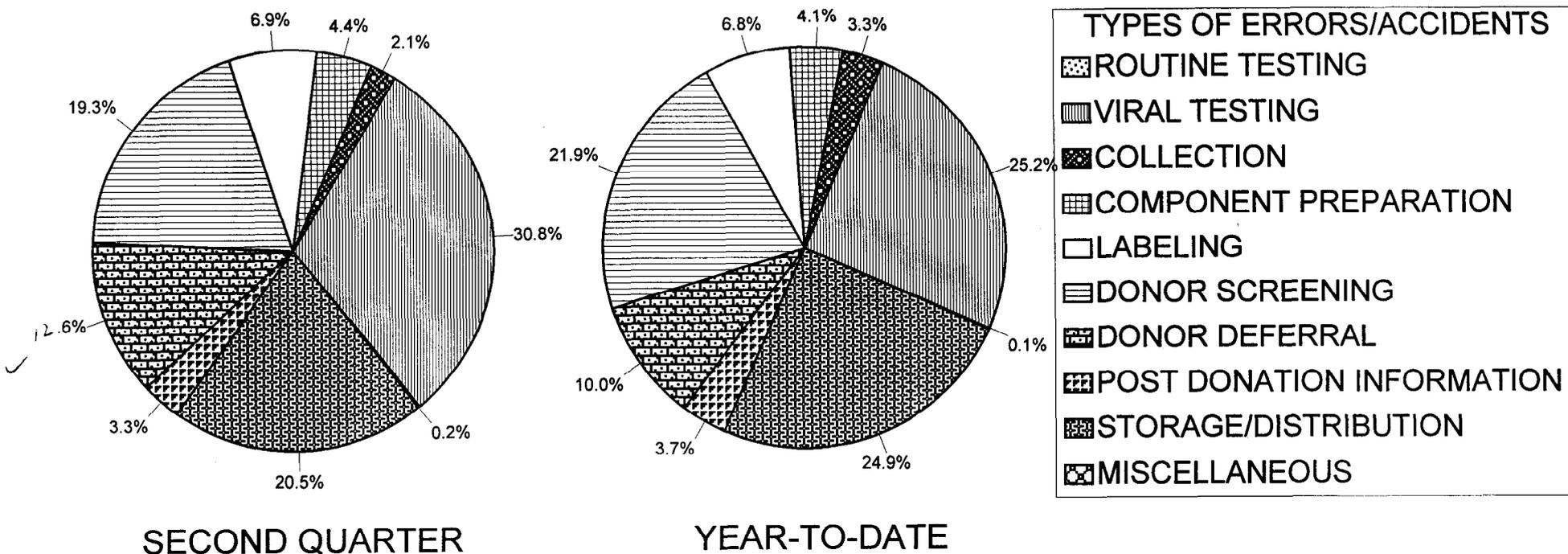
REPORTS RECEIVED SECOND QUARTER (1/1/99 - 3/31/99) = 4060
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 3/31/99) = 7657

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

POTENTIAL RECALLS

FY99

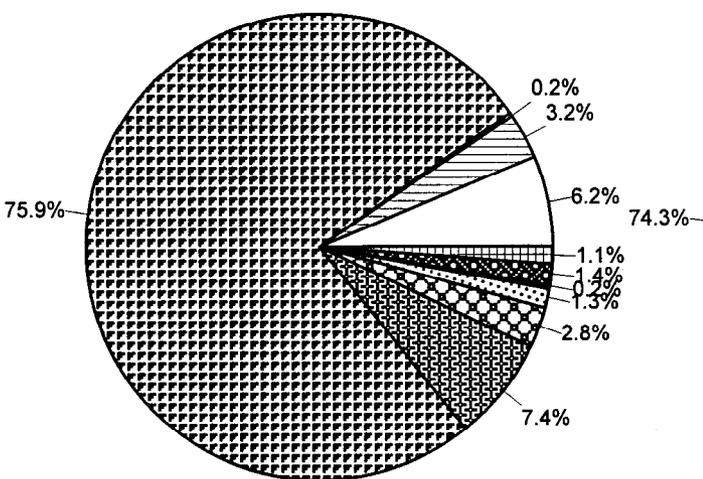


REPORTS RECEIVED SECOND QUARTER (1/1/99 - 3/31/99) = 611
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 3/31/99) = 1098

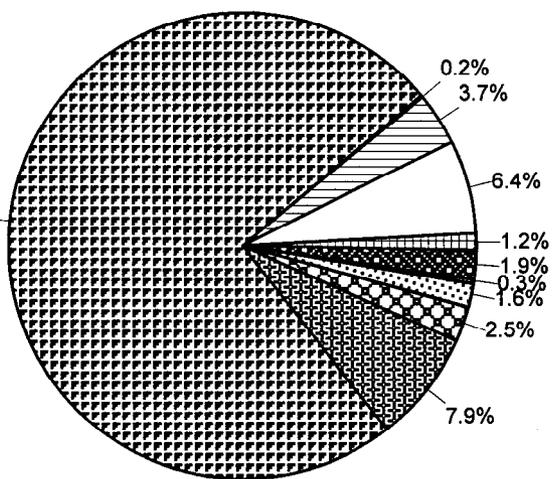
ERROR AND ACCIDENT REPORTS

AMERICAN RED CROSS

FY99



SECOND QUARTER



YEAR-TO-DATE

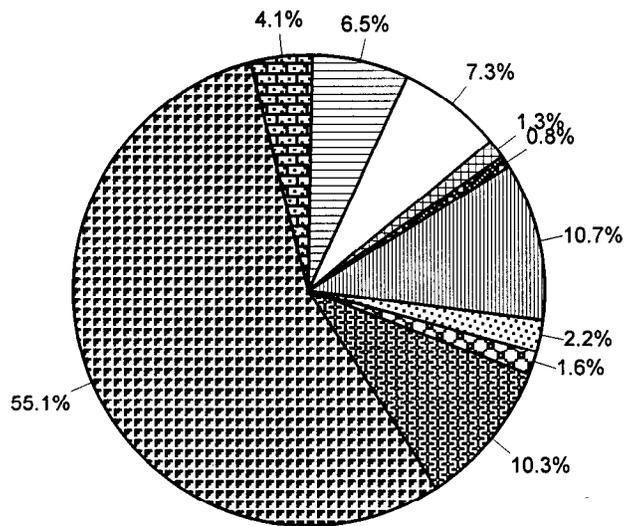
- TYPES OF ERRORS/ACCIDENTS
- ROUTINE TESTING
 - VIRAL TESTING
 - COLLECTION
 - COMPONENT PREPARATION
 - LABELING
 - DONOR SCREENING
 - DONOR DEFERRAL
 - POST DONATION INFORMATION
 - STORAGE/DISTRIBUTION
 - MISCELLANEOUS

REPORTS RECEIVED SECOND QUARTER (1/1/99 - 3/31/99) = 1663
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 3/31/99) = 3298

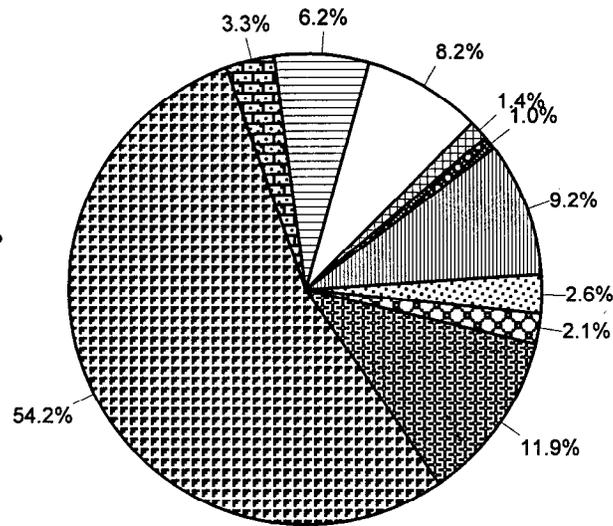
ERROR AND ACCIDENT REPORTS

NON-ARC LICENSED BLOOD BANKS

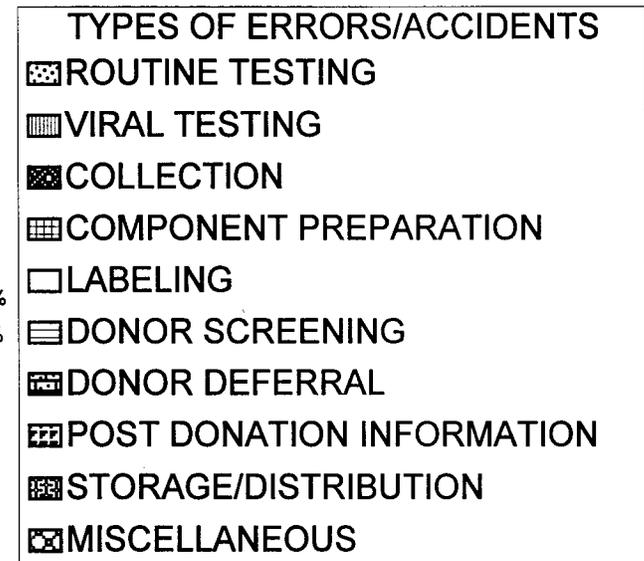
FY99



SECOND QUARTER



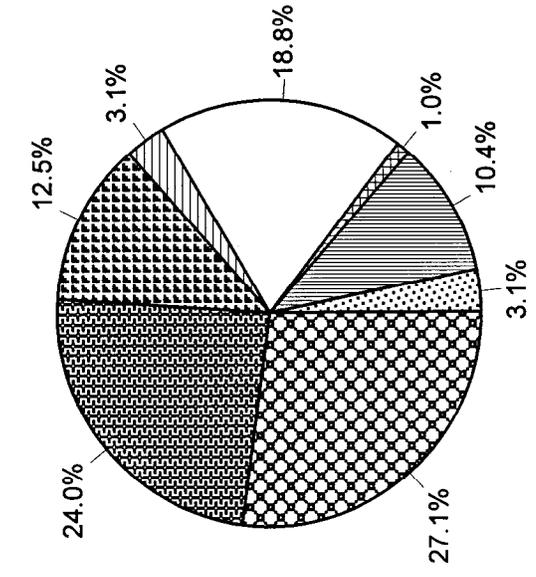
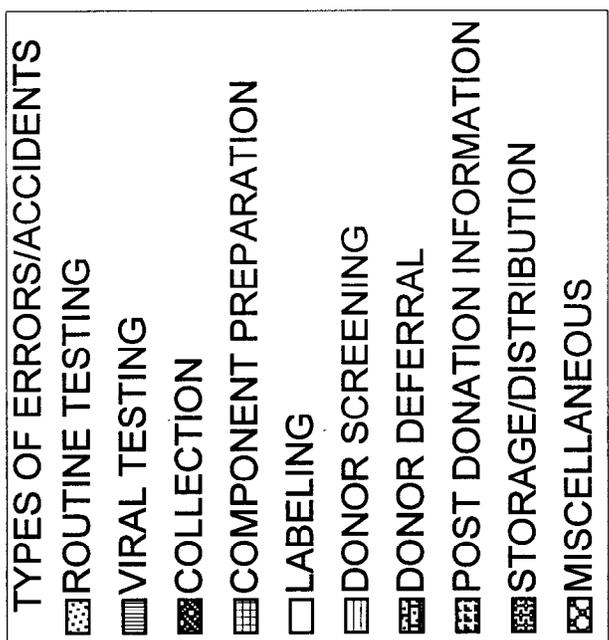
YEAR-TO-DATE



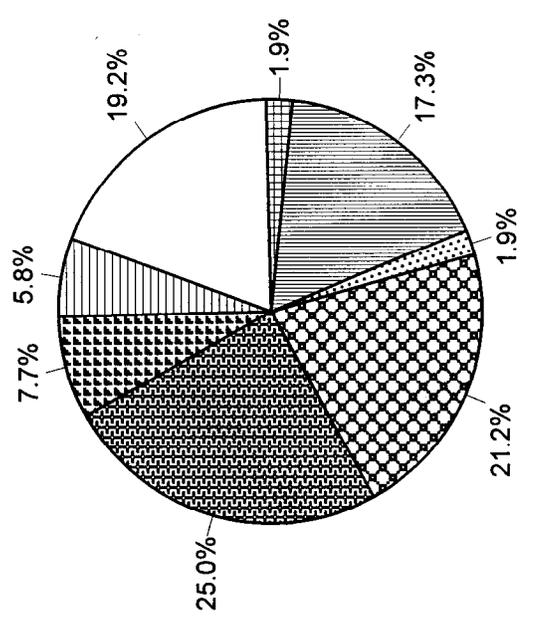
REPORTS RECEIVED SECOND QUARTER (1/1/99 - 3/31/99) = 1808
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 3/31/99) = 3460

ERROR AND ACCIDENT REPORTS UNLICENSED BLOOD BANKS

FY99



YEAR-TO-DATE



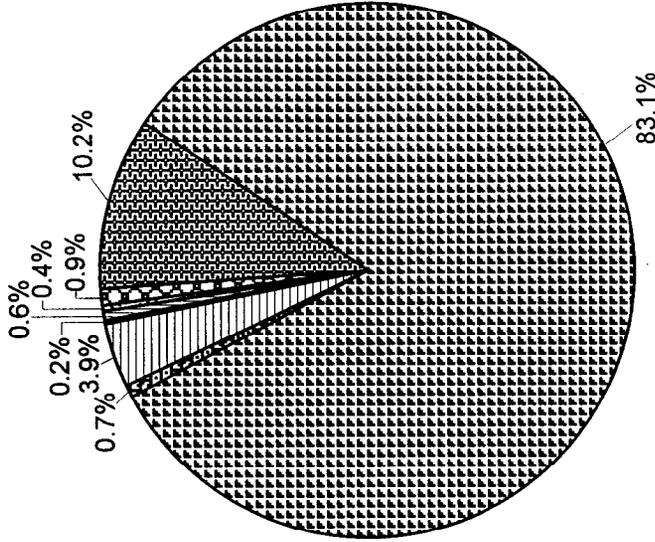
SECOND QUARTER

REPORTS RECEIVED SECOND QUARTER (1/1/99 - 3/31/99) = 52 (6 REPORTS - TRANSFUSION SERVICES)
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 3/31/99) = 96 (10 REPORTS - TRANSFUSION SERVICES)

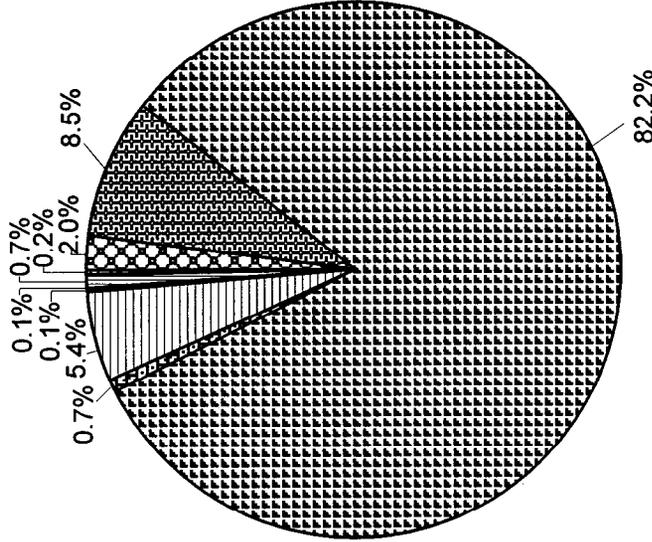
ERROR AND ACCIDENT REPORTS

PLASMA CENTERS

FY99



SECOND QUARTER



YEAR-TO-DATE

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

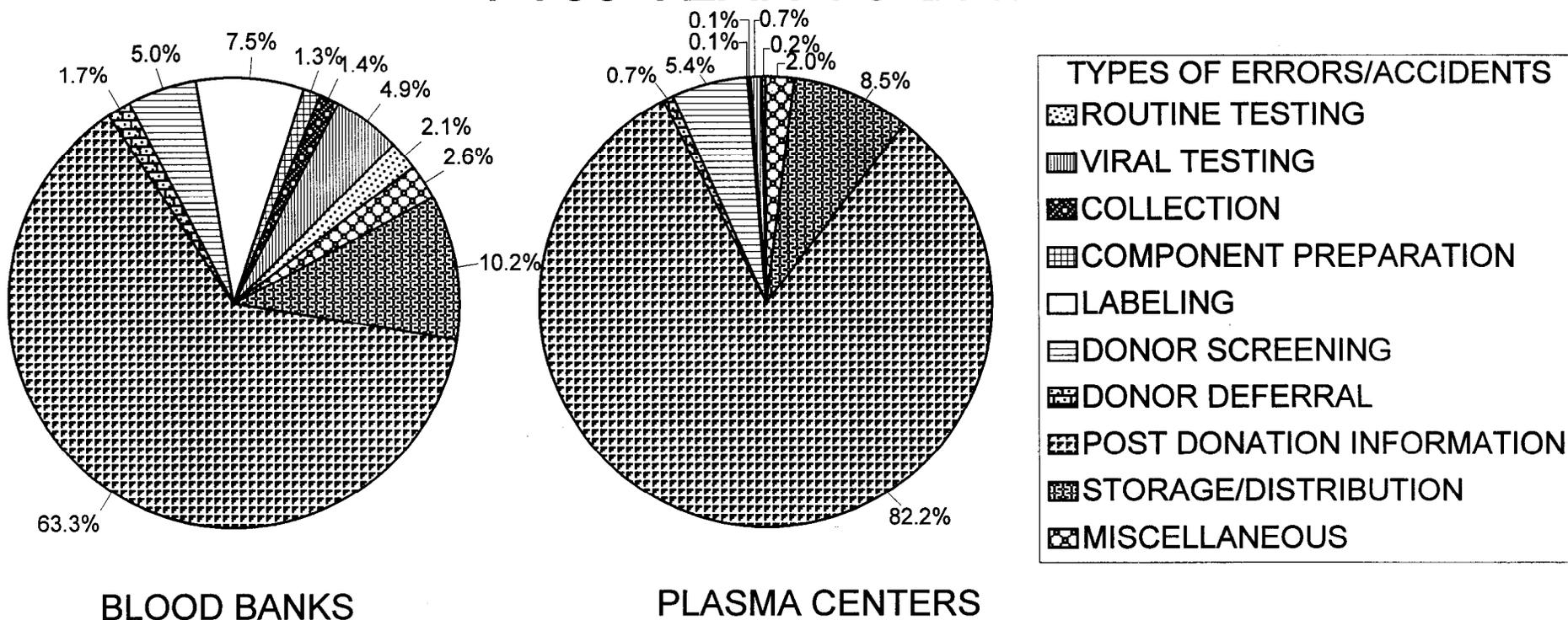
REPORTS RECEIVED SECOND QUARTER (1/1/99 - 3/31/99) = 537

REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 3/31/99) = 803

ERROR AND ACCIDENT REPORTS

BLOOD BANKS VERSUS PLASMA CENTERS

FY99 YEAR-TO-DATE



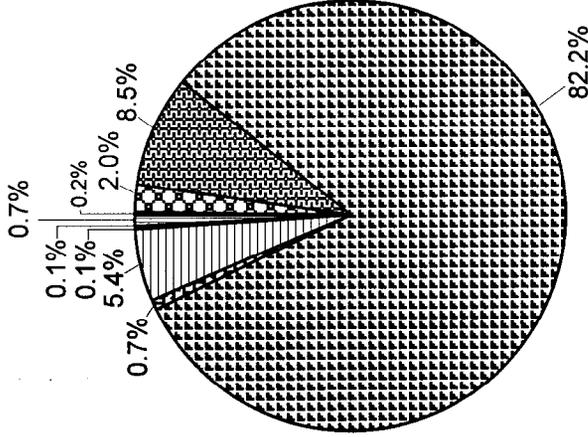
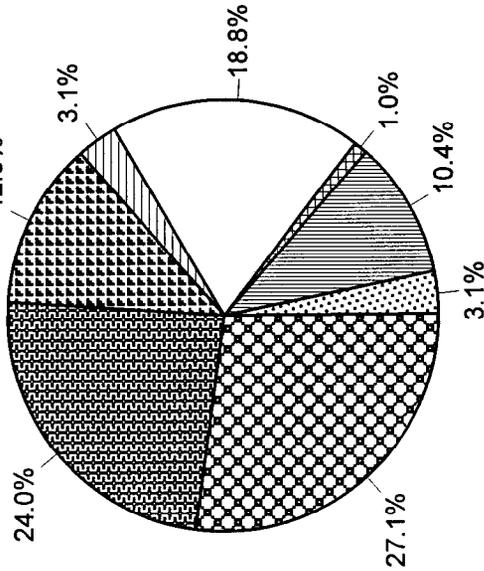
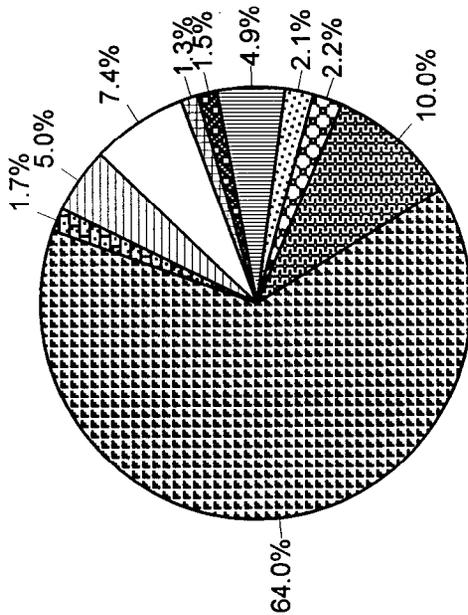
REPORTS RECEIVED 10/1/98 - 3/31/99

BLOOD BANKS = 6854

PLASMA CENTERS = 803

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 - 3/31/99

LICENSED BLOOD BANKS = 6758

UNLICENSED BLOOD BANKS = 96

PLASMA CENTERS = 803

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

TYPE OF ERROR/ACCIDENT	NON-REPORTABLE	REPORTABLE	TOTAL	%NON-REPORTABLE
ROUTINE TESTING	1	63	64	1.6%
VIRAL TESTING	10	200	210	4.8%
COLLECTION	7	32	39	17.9%
COMPONENT PREPARATION	1	44	45	2.2%
LABELING	36	209	245	14.7%
DONOR SCREENING	13	182	195	6.7%
DONOR DEFERRAL	1	82	83	1.2%
POST DONATION INFORMATION	18	2692	2710	0.7%
STORAGE/DISTRIBUTION	21	356	377	5.6%
MISCELLANEOUS	86	6	92	93.5%
TOTAL	194	3866	4060	4.8%

%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	2	146	148	1.4%
VIRAL TESTING	10	334	344	2.9%
COLLECTION	20	78	98	20.4%
COMPONENT PREPARATION	2	85	87	2.3%
LABELING	79	437	516	15.3%
DONOR SCREENING	28	356	384	7.3%
DONOR DEFERRAL	3	121	124	2.4%
POST DONATION INFO	26	4972	4998	0.5%
STORAGE/DISTRIBUTION	35	729	764	4.6%
MISCELLANEOUS	183	11	194	94.3%
TOTAL	388	7269	7657	5.1%

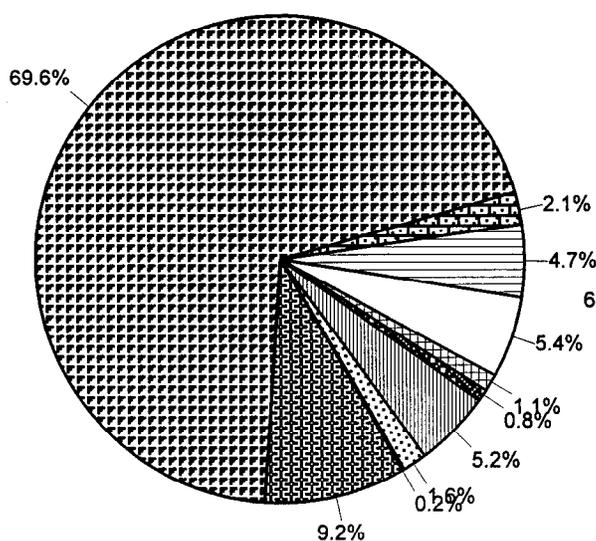
%NON-REPORTABLE = Non-Reportable/Total for each category

ERROR AND ACCIDENT REPORTS

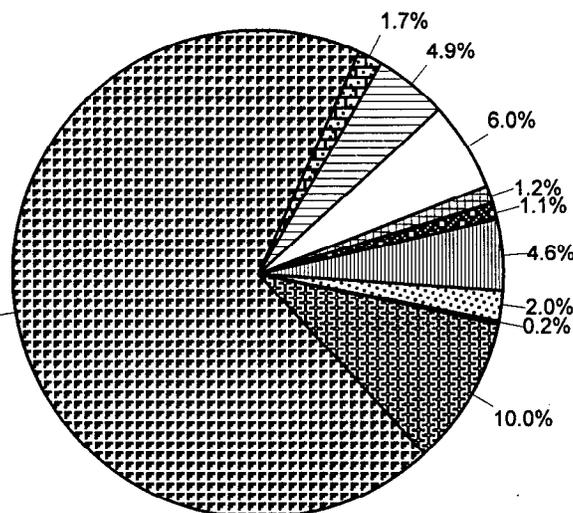
ALL BLOOD AND PLASMA ESTABLISHMENTS

REPORTABLE ERRORS/ACCIDENTS

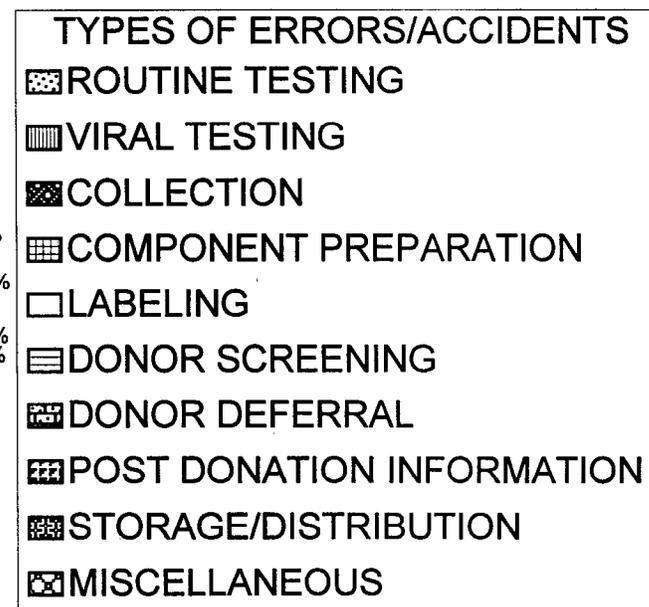
FY99



SECOND QUARTER



YEAR-TO-DATE



REPORTS RECEIVED SECOND QUARTER (1/1/99 - 3/31/99) = 3000
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 3/31/99) = 5899

FY98 YEAR-TO-DATE

REPORTABLE ERRORS/ACCIDENTS - 7269 (94.9% of total reports)

Top Three Categories of Errors/Accidents:

Post Donation Information - 4972 (68.4% of reportables)

**Examples:*

Information provided post donation:

- Donor received tattoo, earpiercing, 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 - 729 (10.0% of reportables)

**Examples:*

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

Labeling - 437 (6.0% of reportables)

**Examples:*

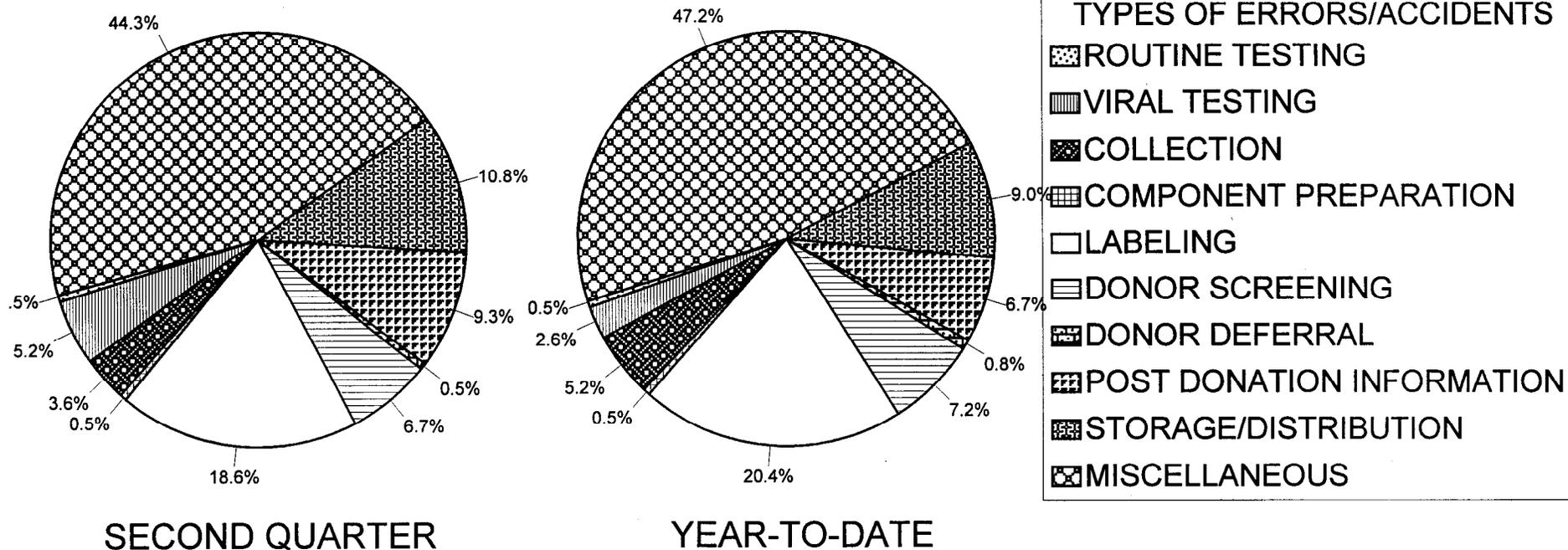
- Additional information on autologous unit incorrect or missing, e.g., name, social security number, or date of birth
- Product labeled with extended expiration date
- Missing or incorrect donor/unit number
- Incorrect ABO/Rh

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

NON-REPORTABLE ERRORS/ACCIDENTS

FY99



REPORTS RECEIVED SECOND QUARTER (1/1/99 - 3/31/99) = 194
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 3/31/99) = 388

FY98 YEAR-TO-DATE

NON-REPORTABLE ERRORS/ACCIDENTS - 388 (5.1% of total reports)

Top Three Categories of Errors/Accidents:

Miscellaneous 183 (47.2% 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 - record is incorrect or not reviewed, testing and labeling acceptable

Labeling - 79 (20.4% of non-reportables)

**Examples:*

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

Storage and Distribution 35 (9.0% of non-reportables)

**Example:*

- Irradiation requested by customer, unit not irradiated, labeled appropriately
- Discrepancy between shipping form and shipment
- Failure to quarantine a unit after receiving information of post donation cold/flu symptoms

*Examples of errors and accidents represent at least 50% of reports in each category.

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
SECOND QUARTER - FY99

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

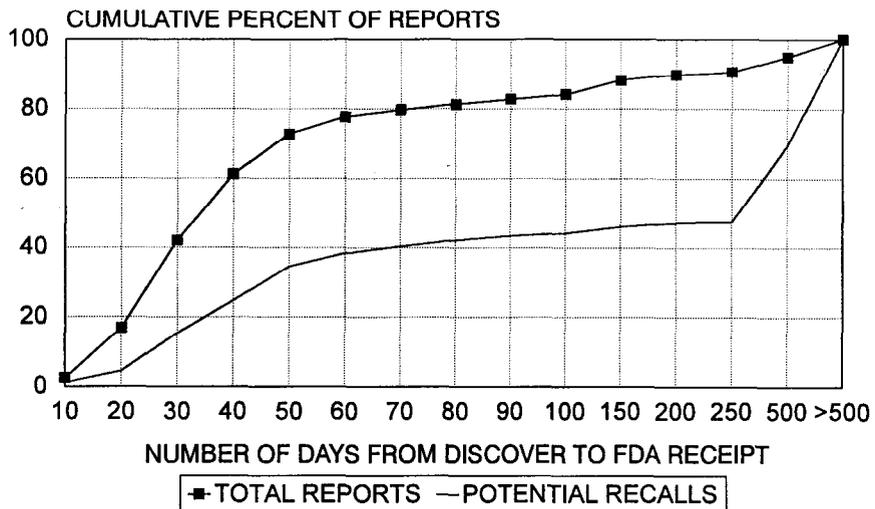
CUMULATIVE PERCENT OF REPORTS	ARC (DAYS)	NON-ARC LICENSED (DAYS)	UNLICENSED (DAYS)	PLASMA (DAYS)	TOTAL (DAYS)
10%	18	17	9	13	16
25%	23	24	20	19	23
50%	31	41	59	32	34
75%	39	114	198	73	53
90%	48	670	823	259	210
# REPORTS	1563	1728	37	532	3860
RANGE	5-384	4-2133	5-832	5-1222	4-2133

ERROR AND ACCIDENT REPORTS
RECEIVED 10/1/98 - 3/31/99

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

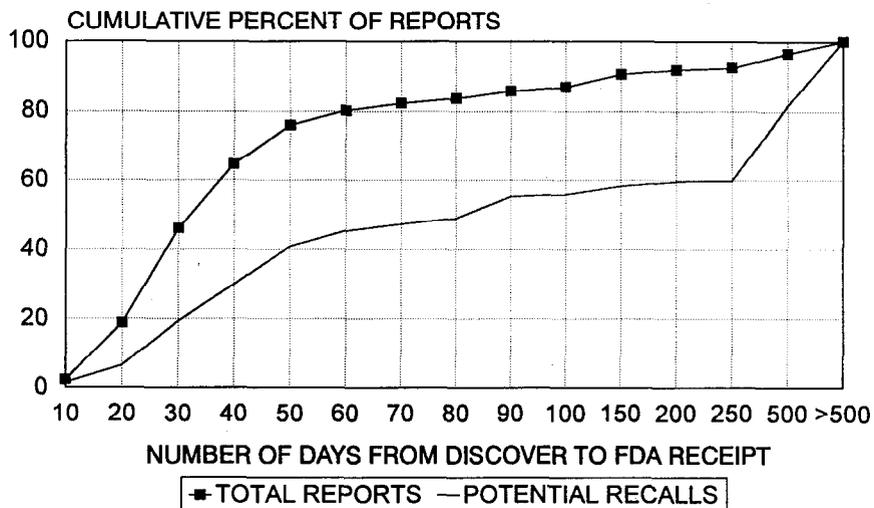
CUMULATIVE PERCENT OF REPORTS	ARC (DAYS)	NON-ARC LICENSED (DAYS)	UNLICENSED (DAYS)	PLASMA (DAYS)	TOTAL (DAYS)
10%	16	16	8	13	16
25%	22	23	15	18	22
50%	29	38	26	28	32
75%	38	96	71	55	49
90%	47	412	227	221	134
# REPORTS	3104	3302	54	783	7243
RANGE	5-384	4-2133	5-832	5-1222	4-2133

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



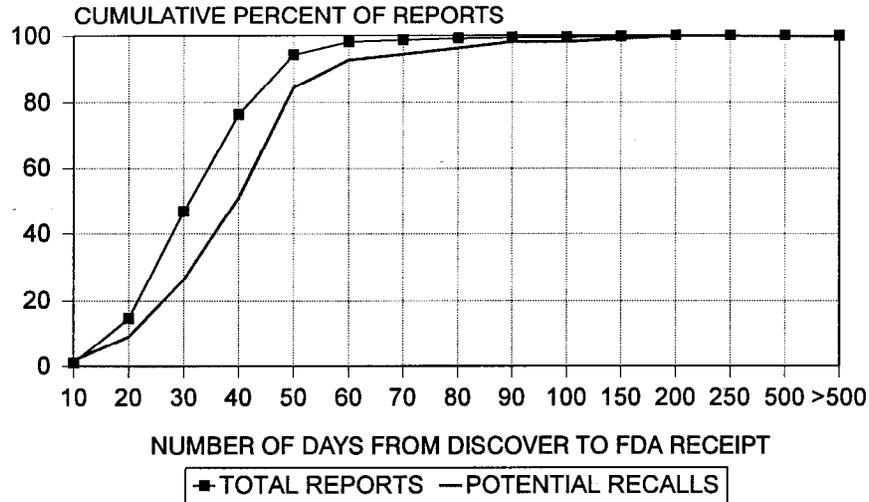
TOTAL REPORTS = 3860
POTENTIAL RECALLS = 611

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



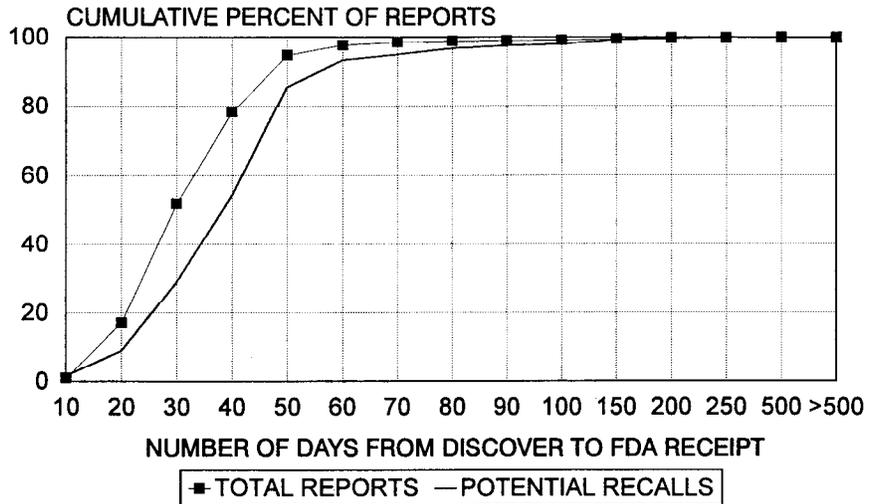
TOTAL REPORTS = 7243
POTENTIAL RECALLS = 1102

ERROR AND ACCIDENT REPORTS REPORTING TIME AMERICAN RED CROSS SECOND QUARTER FY99



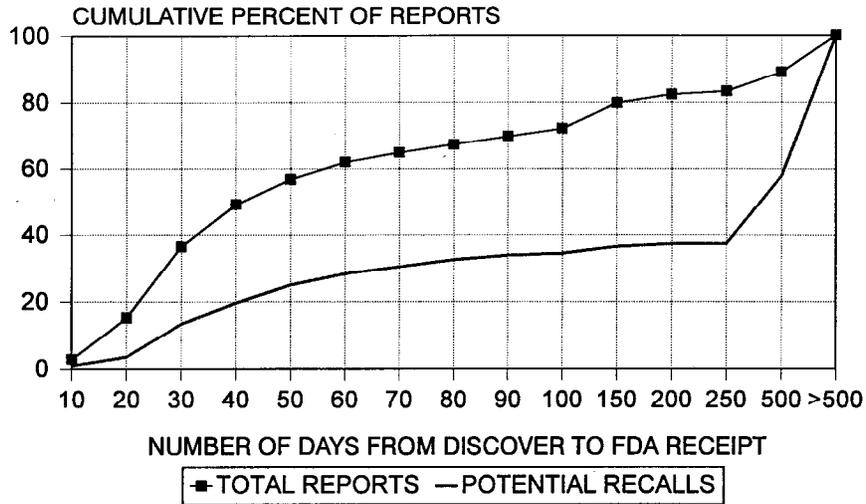
TOTAL REPORTS = 1563
POTENTIAL RECALLS = 110

ERROR AND ACCIDENT REPORTS REPORTING TIME AMERICAN RED CROSS YEAR-TO-DATE FY99



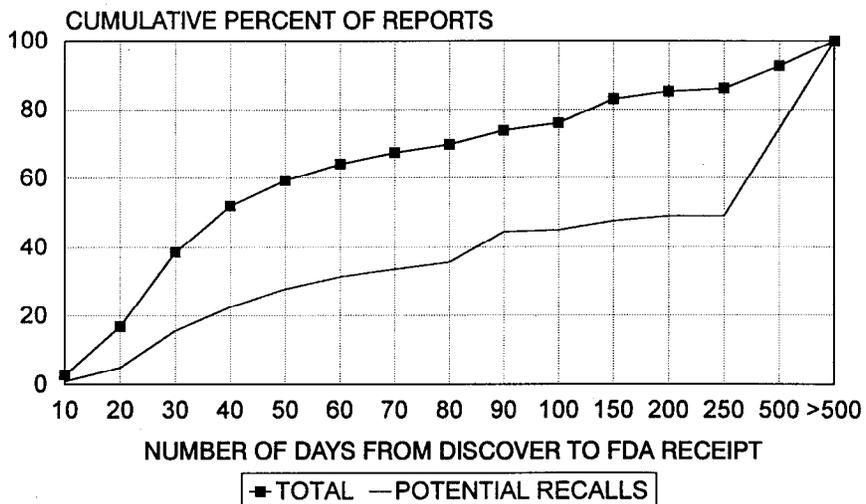
TOTAL REPORTS = 3104
POTENTIAL RECALLS = 234

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



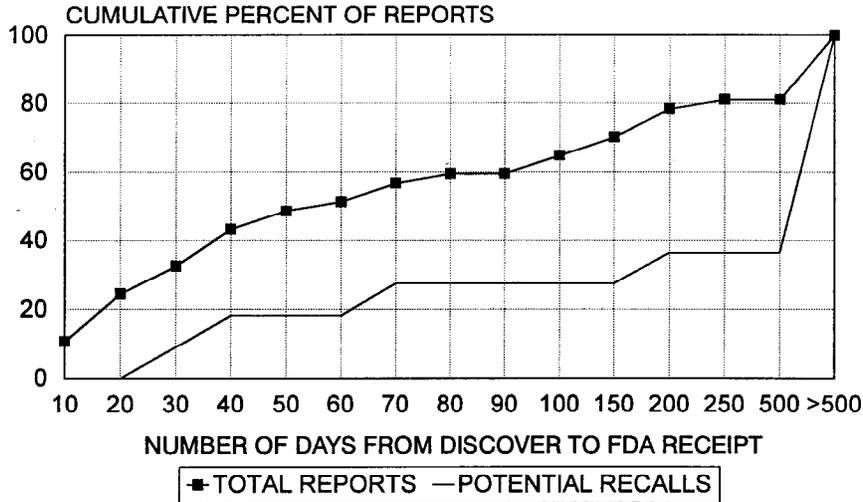
TOTAL REPORTS = 1728
POTENTIAL RECALLS = 429

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



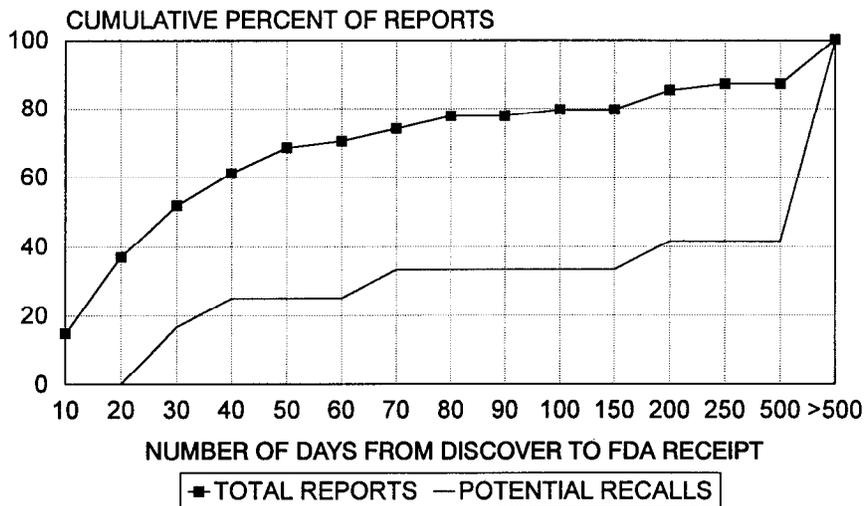
TOTAL REPORTS = 3302
POTENTIAL RECALLS = 767

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



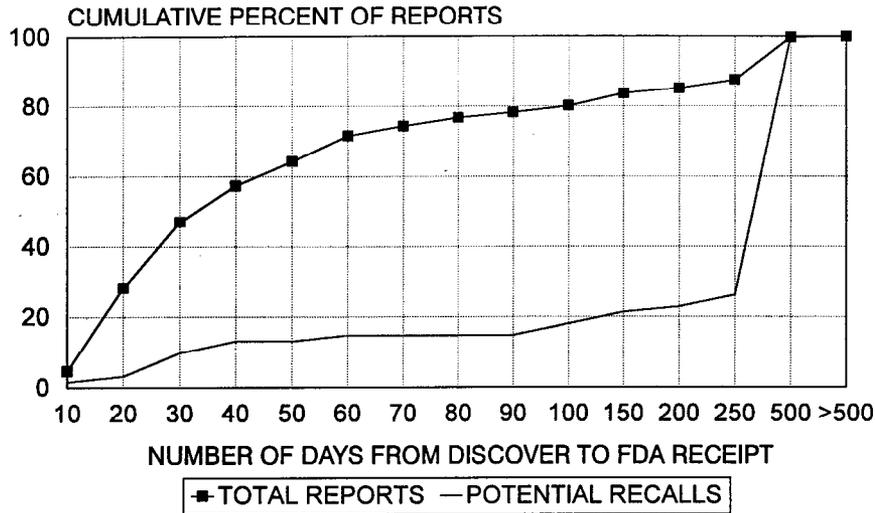
TOTAL REPORTS = 37
POTENTIAL RECALLS = 11

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



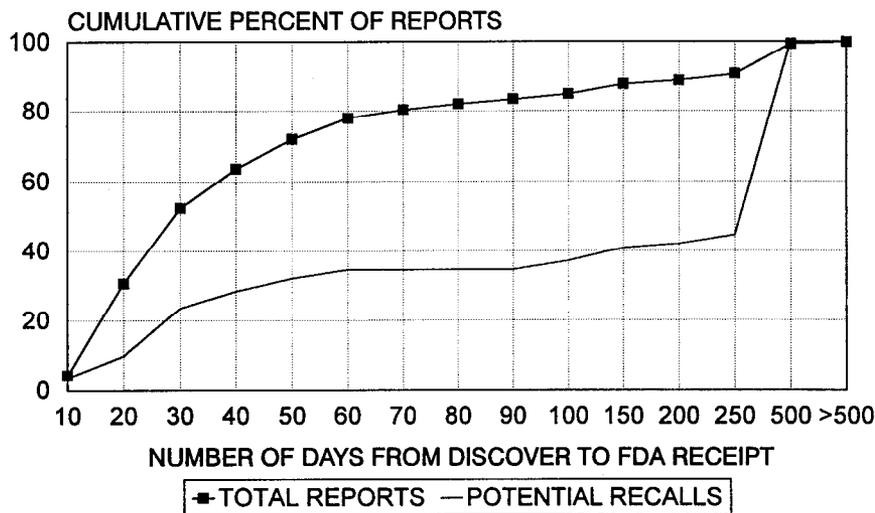
TOTAL REPORTS = 54
POTENTIAL RECALLS = 12

ERROR AND ACCIDENT REPORTS REPORTING TIME PLASMA CENTERS SECOND QUARTER FY99



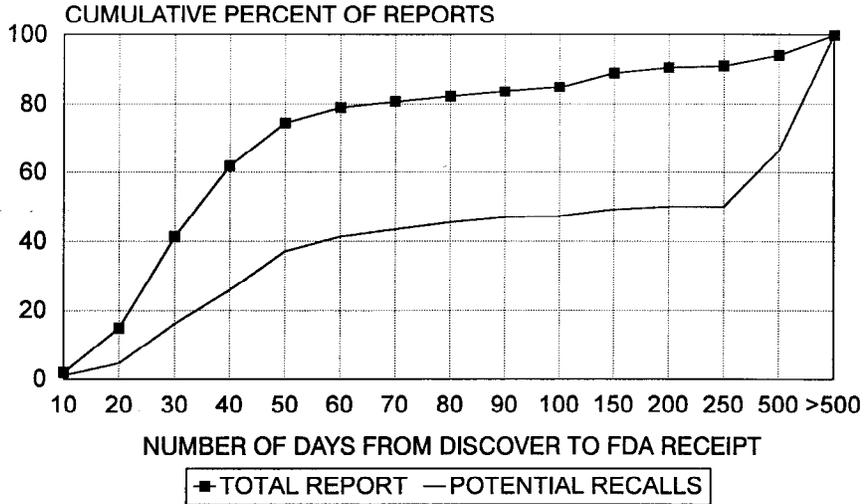
TOTAL REPORTS = 532
POTENTIAL RECALLS = 61

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



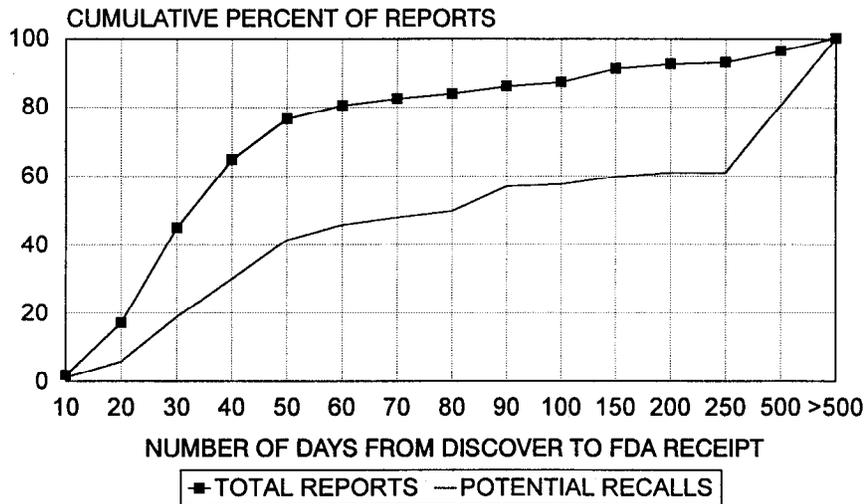
TOTAL REPORTS = 783
POTENTIAL RECALLS = 81

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



TOTAL REPORTS = 3291
POTENTIAL RECALLS = 539

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



TOTAL REPORTS = 6406
POTENTIAL RECALLS = 1001