

MEMORANDUM

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

DATE: **MAR 23 1999**

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

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

TO: Acting Director, Division of Inspections and Surveillance (HFM-650) *J. Salewski*

Between October 1, 1998 and December 31, 1998, the Division of Inspections and Surveillance received 1,635 error and accident reports from the American Red Cross (ARC), 1,652 error and accident reports from non-ARC licensed blood establishments, 40 error and accident reports from unlicensed registered blood establishments, 266 error and accident reports from plasma centers, 4 reports from transfusion services, 7 reports from blood derivative manufacturers, 2 reports from in-vitro diagnostic manufacturers, 1 report from an allergenic manufacturer, and 3 reports from therapeutic manufacturers. A total of 3,610 error and accident reports were received. There were 493 (13.7%) 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, 194 (5.4%) 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
- 4 - Pie charts - All Blood and Plasma Establishments
Total, Potential Recalls
- 5 - Pie charts - Types of Errors/Accidents - Total Reports
ARC, Non-ARC Licensed Blood Banks
- 6 - Pie charts - Types of Errors/Accidents - Total Reports
Unlicensed Blood Banks, Plasma Centers
- 7 - Pie charts - Types of Errors/Accidents - Total Reports
Blood Banks, Plasma Centers
- 8 - Pie charts - Types of Errors/Accidents - Total Reports
Licensed Blood Banks, Unlicensed Blood Banks, Plasma Centers
- 9 - Table - Types of Errors/Accidents
Blood and Plasma Establishments - Non-Reportable, Reportable, Total
- 10 - Pie charts - Types of Errors/Accidents
Reportable E/A's, Non-Reportable E/A's
- 11 - List - Top Three Categories of Reportable Errors/Accidents
Year-To-Date
- 12 - List - Top Three Categories of Non-Reportable Errors/Accidents
Year-To-Date
- 13 - Table - Reporting Time
- 14 - Line graphs - Reporting Time
ARC, Non-ARC Licensed Blood Banks
- 15 - Line graphs - Reporting Time
Unlicensed Blood Banks, Plasma Centers
- 16 - Line graphs - Reporting Time
All Reporting Blood Establishments, All Licensed Blood Establishments

**FIRST QUARTER FY99
ALL REPORTING ESTABLISHMENTS**

	TOTAL REPORTS	POTENTIAL RECALLS
AMERICAN RED CROSS	1635	125
NON-ARC LICENSED BLOOD BANKS	1652	340
UNLICENSED BLOOD BANKS	40	2
TRANSFUSION SERVICES	4	0
PLASMA CENTERS	266	20
BLOOD DERIVATIVE MANUFACTURER	7	1
IN-VITRO DIAGNOSTIC MANUFACTURER	2	2
VACCINE MANUFACTURER	0	0
ALLERGENICS MANUFACTURER	1	1
THERAPEUTIC MANUFACTURER	3	2
TOTAL	3610	493

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

**FIRST 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	31	51	2	0	0	84	2.3%
VIRAL TESTING	5	125	1	0	3	134	3.7%
COLLECTION	40	19	0	0	0	59	1.6%
COMPONENT PREPARATION	19	21	0	0	0	40	1.1%
LABELING	109	153	8	0	1	271	7.5%
DONOR SCREENING	69	98	0	0	22	189	5.3%
DONOR DEFERRAL	1	38	0	0	2	41	1.1%
POST DONATION INFOR	1189	877	8	0	214	2288	63.6%
STORAGE/DISTRIBUTION	138	228	7	3	13	389	10.8%
MISCELLANEOUS	34	42	14	1	11	102	2.8%
TOTAL	1635	1652	40	4	266	3597	100%

POTENTIAL RECALLS

TYPE OF ERROR/ACCIDENT	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
ROUTINE TESTING	0	0	0	0	0	0	0.0%
VIRAL TESTING	1	86	1	0	1	89	18.3%
COLLECTION	10	13	0	0	0	23	4.7%
COMPONENT PREPARATION	9	8	0	0	0	17	3.5%
LABELING	12	21	0	0	0	33	6.8%
DONOR SCREENING	45	65	0	0	12	122	25.1%
DONOR DEFERRAL	0	32	0	0	1	33	6.8%
POST DONATION INFO	18	3	0	0	0	21	4.3%
STORAGE/DISTRIBUTION	30	112	1	0	6	149	30.6%
MISCELLANEOUS	0	0	0	0	0	0	0.0%
TOTAL	125	340	2	0	20	487	100%

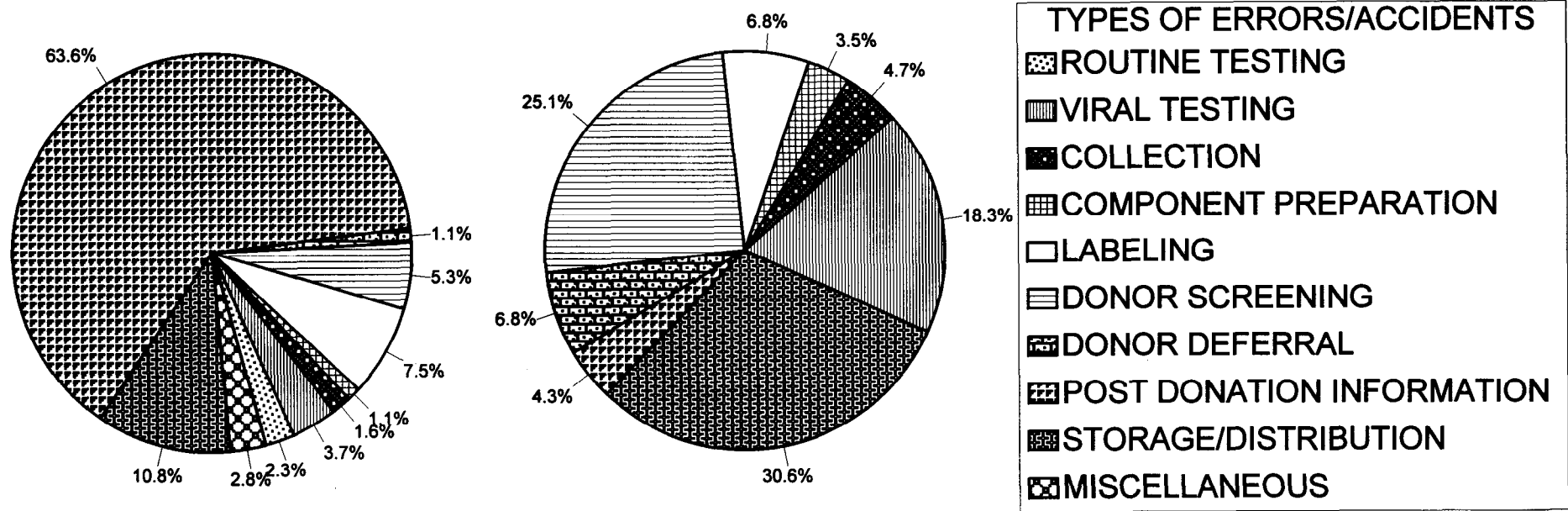
**FIRST QUARTER - FY99
NON-BLOOD MANUFACTURERS**

TYPE OF ERROR/ACCIDENT	DERIVATIVE		IN-VITRO DIAGNOSTIC		ALLERGENIC		THERAPEUTIC		TOTAL		RECALL	
	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL				
REAGENT PERFORMANCE	0	0	1	1	0	0	0	0	1	7.7%	1	16.7%
STERILITY COMPROMISED	0	0	0	0	0	0	2	2	2	15.4%	2	33.3%
LABELING	0	0	1	1	1	1	0	0	2	15.4%	2	33.3%
STORAGE/DISTRIBUTION	1	0	0	0	0	0	0	0	1	7.7%	0	0.0%
MISCELLANEOUS	6	1	0	0	0	0	1	0	7	53.8%	1	16.7%
TOTAL	7	1	2	2	1	1	3	2	13	100.0%	6	100.0%

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

FIRST QUARTER - FY99

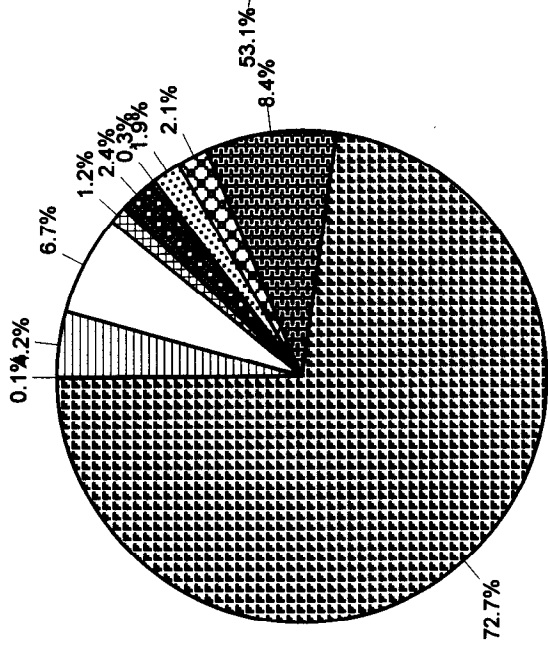


TOTAL REPORTS

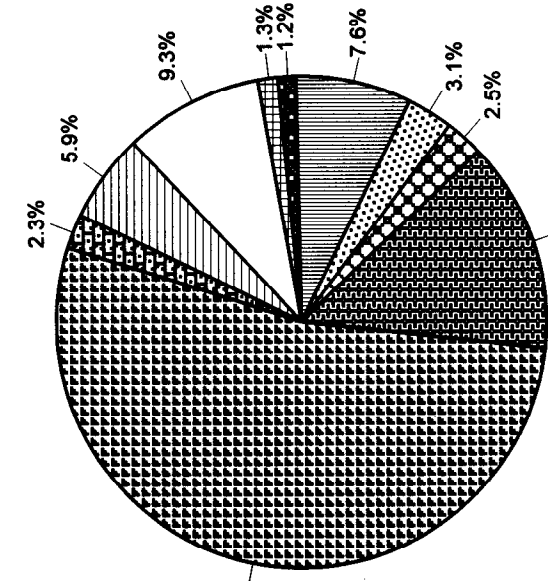
POTENTIAL RECALLS

TOTAL REPORTS RECEIVED (10/1/98 - 12/31/98) = 3597
 POTENTIAL RECALLS = 487

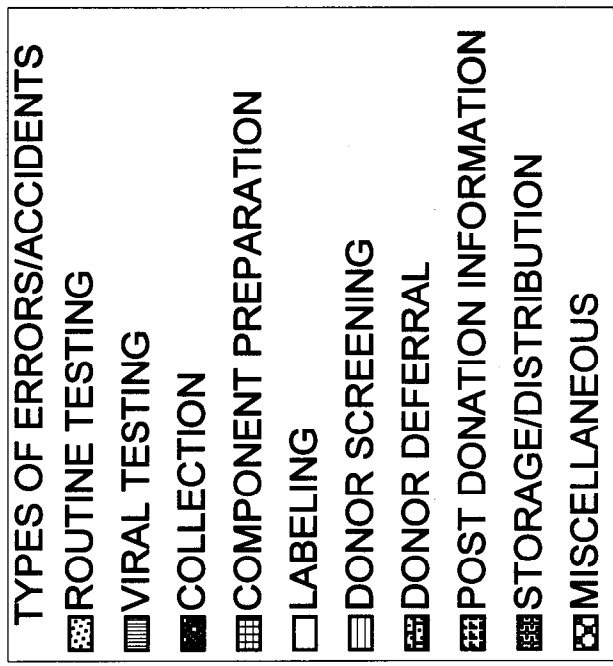
ERROR AND ACCIDENT REPORTS FIRST QUARTER FY99



AMERICAN RED CROSS



NON-ARC LICENSED BLOOD BANKS

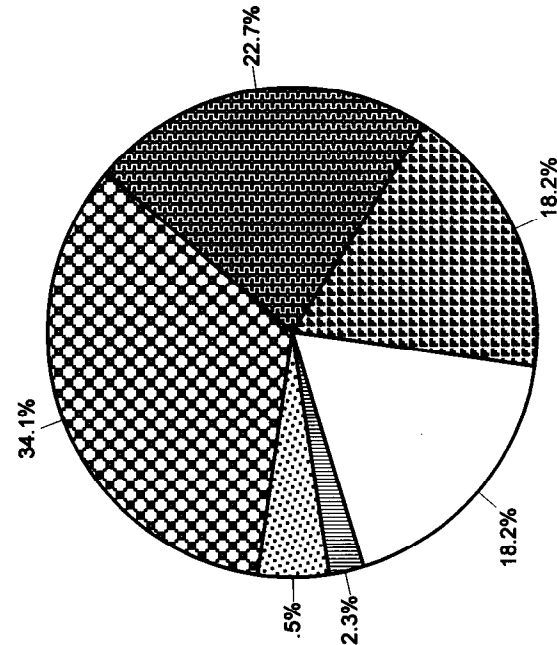


REPORTS RECEIVED (10/1/98 - 12/31/98)
 AMERICAN RED CROSS = 1635
 NON-ARC LICENSED BLOOD BANKS = 1652

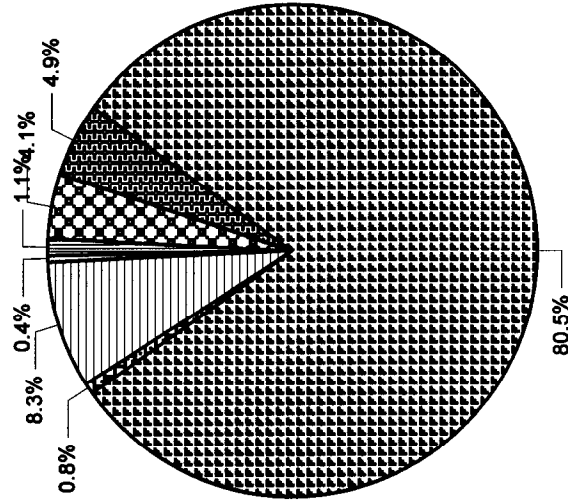
ERROR AND ACCIDENT REPORTS

FIRST QUARTER

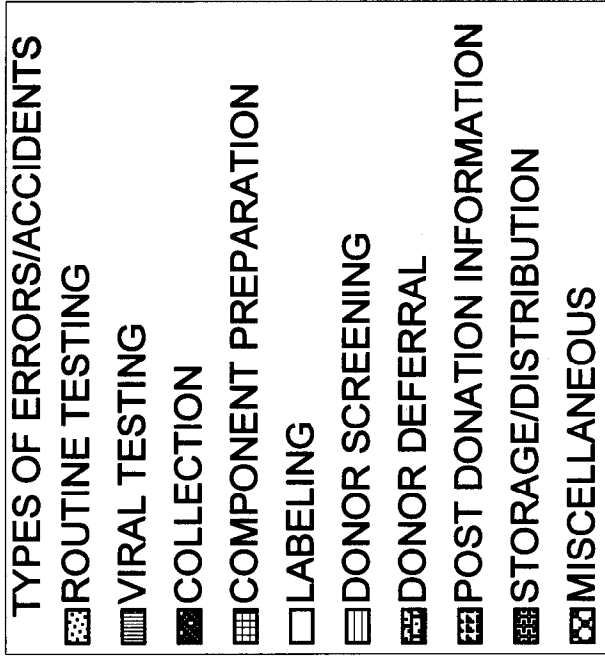
FY99



UNLICENSED BLOOD BANKS



PLASMA CENTERS

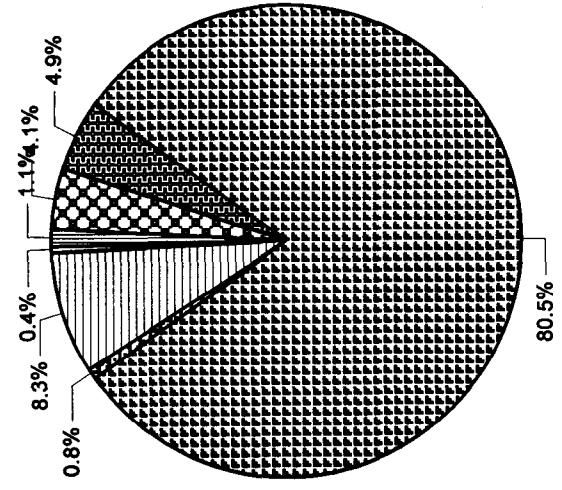
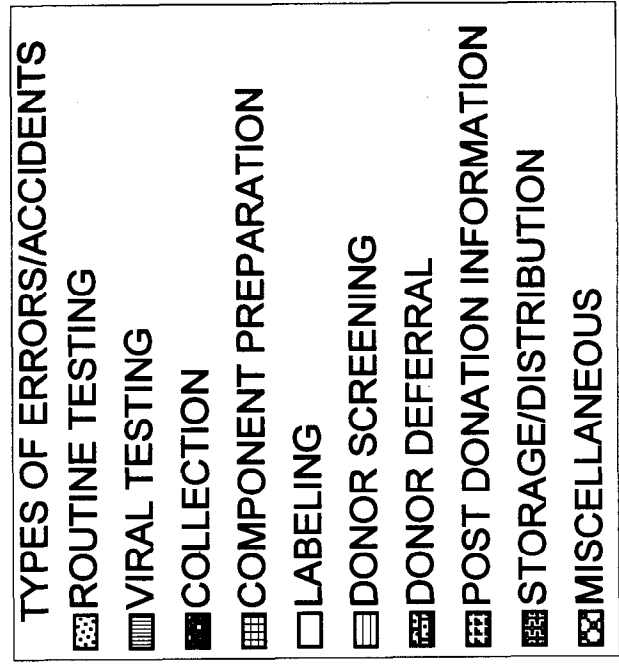


REPORTS RECEIVED (10/1/98 - 12/31/98)
 UNLICENSED BLOOD BANKS = 44 (4 REPORTS - TRANSFUSION SERVICE)
 PLASMA CENTERS = 266

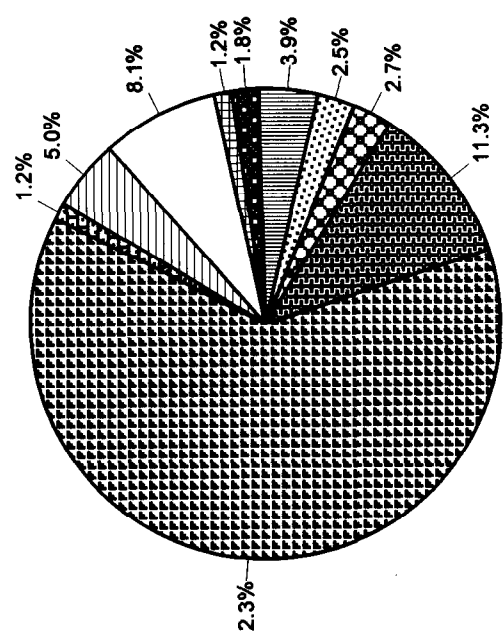
ERROR AND ACCIDENT REPORTS

FIRST QUARTER

FY99



PLASMA CENTERS



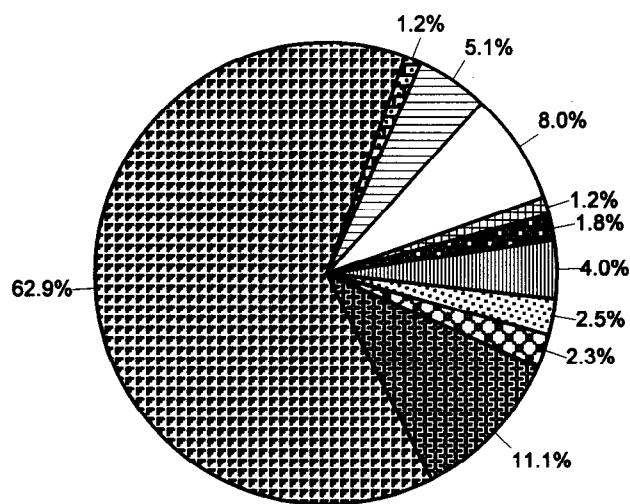
BLOOD BANKS

REPORTS RECEIVED 10/1/98 - 12/31/98
 BLOOD BANKS = 3331
 PLASMA CENTERS = 266

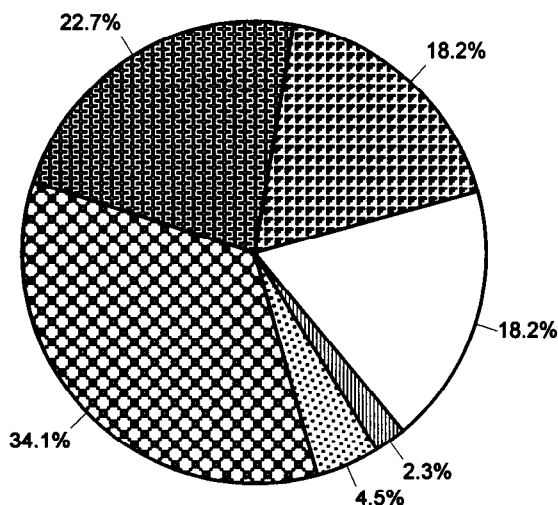
ERROR AND ACCIDENT REPORTS

BLOOD BANKS VERSUS PLASMA CENTERS

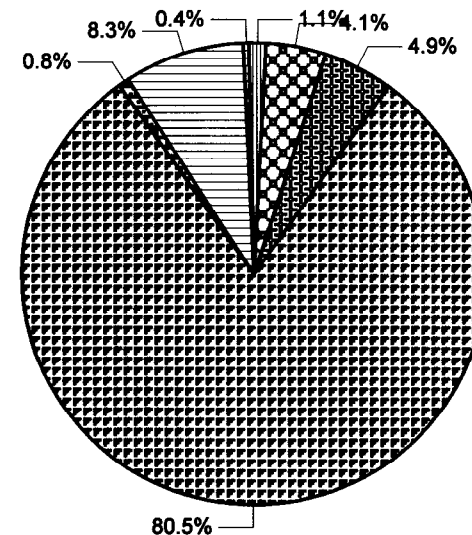
FIRST QUARTER FY99



LICENSED BLOOD BANKS



UNLICENSED BLOOD BANKS



PLASMA CENTERS

TYPES OF ERRORS/ACCIDENTS

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

REPORTS RECEIVED 10/1/98 - 12/31/98
 LICENSED BLOOD BANKS = 3287
 UNLICENSED BLOOD BANKS = 44
 PLASMA CENTERS = 266

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

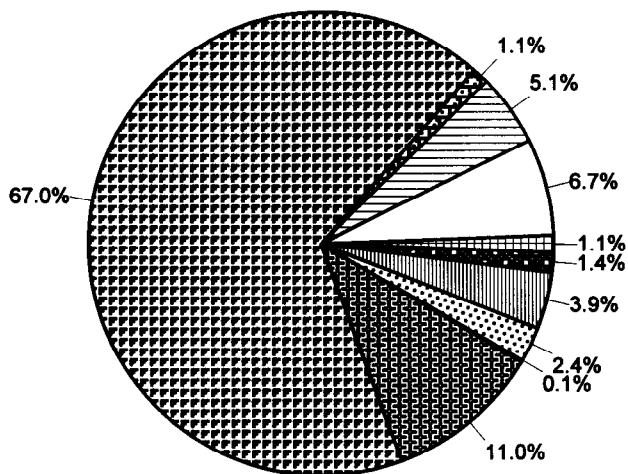
TYPE OF ERROR/ACCIDENT	NON-REPORTABLE	REPORTABLE	TOTAL	%NON-REPORTABLE
ROUTINE TESTING	1	83	84	1.2%
VIRAL TESTING	0	134	134	0.0%
COLLECTION	13	46	59	22.0%
COMPONENT PREPARATION	1	39	42	2.5%
LABELING	43	228	271	15.9%
DONOR SCREENING	15	174	189	7.9%
DONOR DEFERRAL	2	39	41	4.9%
POST DONATION INFORMATION	8	2280	2288	0.3%
STORAGE/DISTRIBUTION	14	375	387	3.6%
MISCELLANEOUS	97	5	102	95.1%
TOTAL	194	3403	3597	5.4%

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

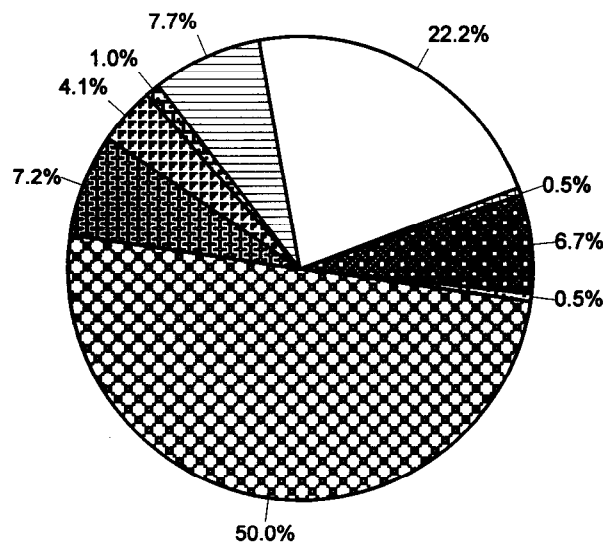
ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

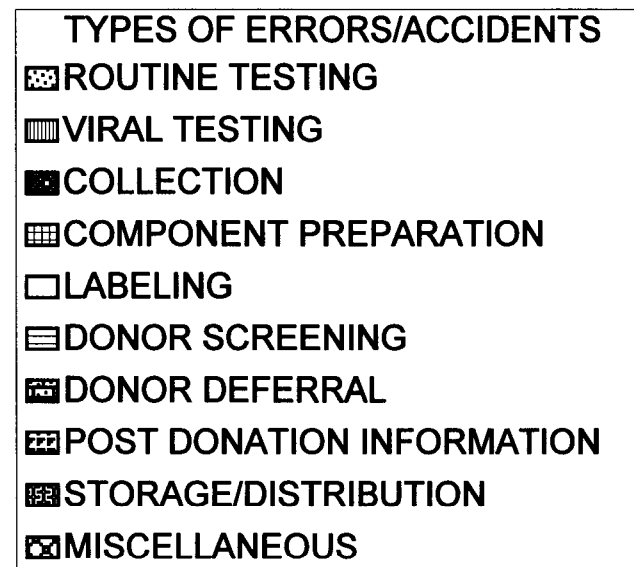
FIRST QUARTER - FY99



REPORTABLE E/A'S



NON-REPORTABLE E/A'S



REPORTS RECEIVED (10/1/98 - 12/31/98)
 REPORTABLE ERRORS/ACCIDENTS = 3403
 NON-REPORTABLE ERRORS/ACCIDENTS = 194

FY99 YEAR-TO-DATE

REPORTABLE ERRORS/ACCIDENTS - 3403 (94.6% of total reports)

Top Three Categories of Errors/Accidents:

Post Donation Information - 2280 (67.0% 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 - 373 (11.0% 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 testing not performed or documented

Labeling - 228 (6.7% 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

FY99 YEAR-TO-DATE

NON-REPORTABLE ERRORS/ACCIDENTS - 194 (5.4% of total reports)

Top Three Categories of Errors/Accidents:

Miscellaneous 97 (50.0% of non-reportables)

**Examples:*

- No products made available for distribution
- Notification/retrieval procedures not followed

Labeling - 43 (22.2% of non-reportables)

**Examples:*

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

Storage/Distribution - 14 (7.2% of non-reportables)

**Example:*

- Discrepancy between shipping form and shipment
- Irradiation requested by customer, unit not irradiated, labeled appropriately

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

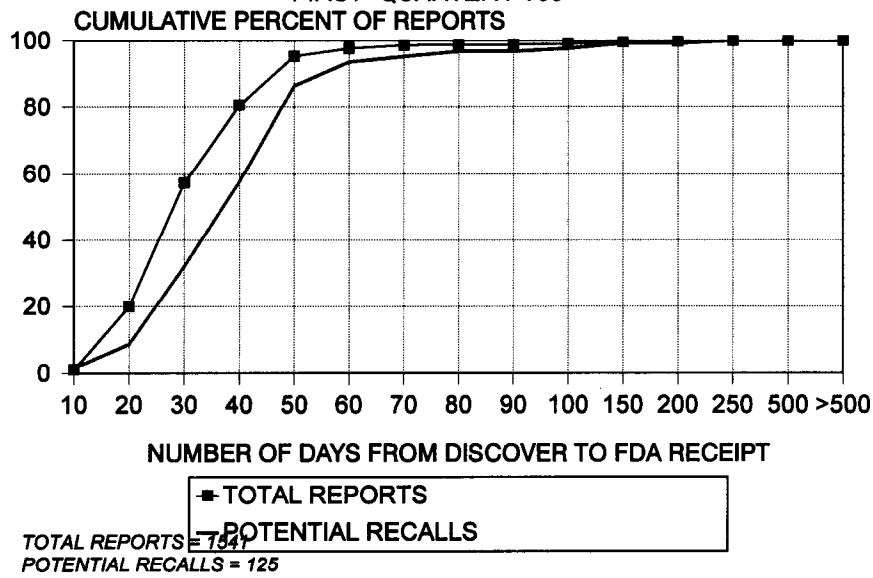
The following table and graphs show the time periods in which the reports were received by CBER. The evaluation of timeliness is limited to only reports that met the threshold for reporting.

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

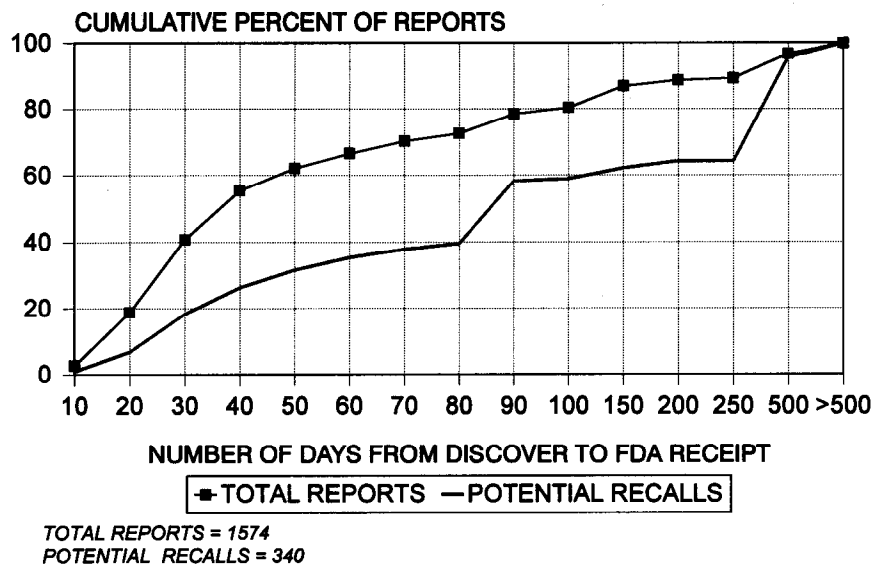
**NUMBER OF DAYS FROM DATE E/A DISCOVERED TO FDA RECEIVED
BLOOD ESTABLISHMENTS**

CUMULATIVE PERCENT OF REPORTS	ARC (DAYS)	NON-ARC LICENSED (DAYS)	UNLICENSED (DAYS)	PLASMA (DAYS)	TOTAL (DAYS)
10%	16	16	6	13	15
25%	21	22	11	17	21
50%	28	35	19	24	30
75%	37	81	26	38	46
90%	46	275	49	52	99
# REPORTS	1541	1574	26	251	3392
RANGE	7-372	5-1170	5-71	5-716	5-1170

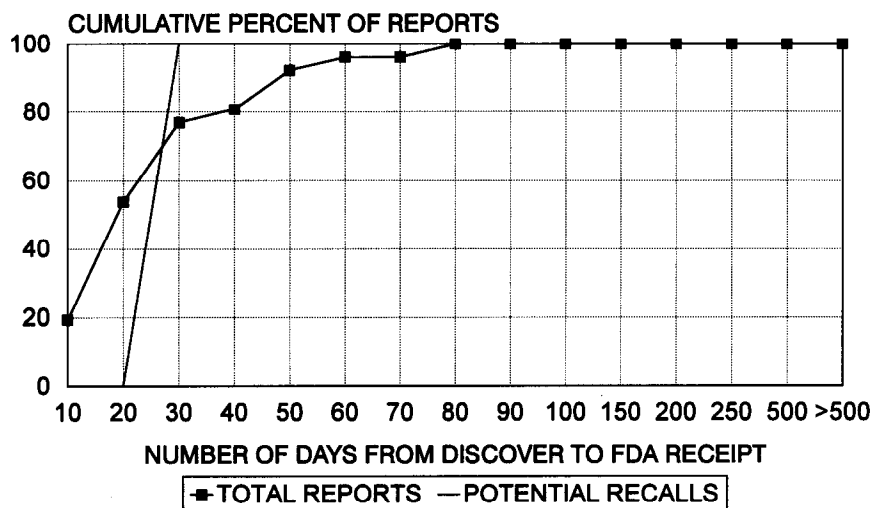
ERROR AND ACCIDENT REPORTS REPORTING TIME AMERICAN RED CROSS FIRST QUARTER FY99



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

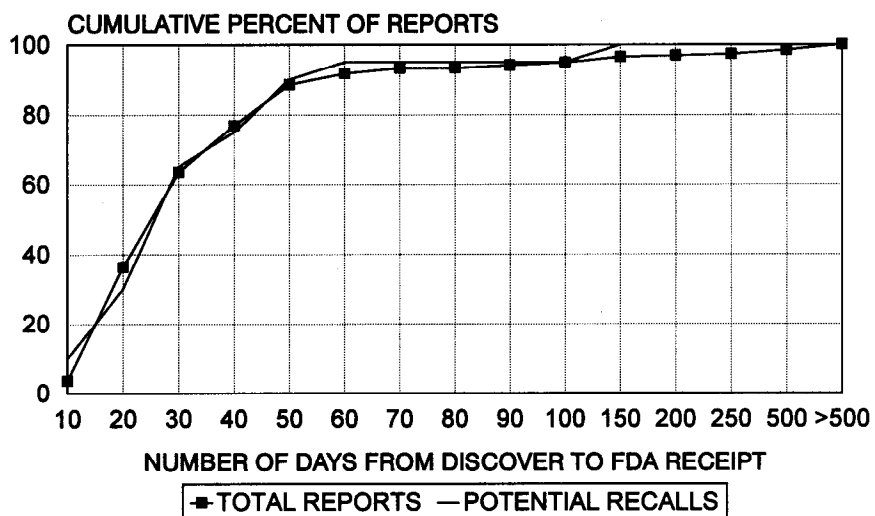


ERROR AND ACCIDENT REPORTS REPORTING TIME UNLICENSED BLOOD BANKS FIRST QUARTER FY99



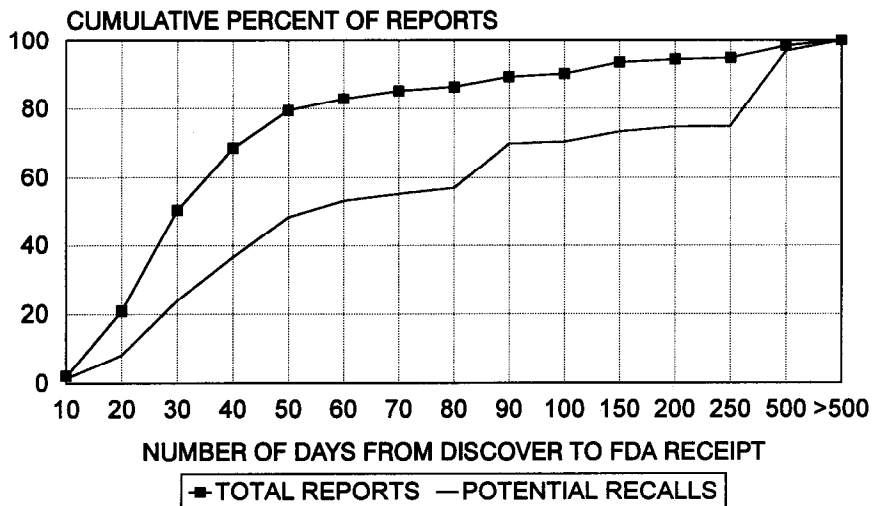
TOTAL REPORTS = 26
POTENTIAL RECALLS = 2

ERROR AND ACCIDENT REPORTS REPORTING TIME PLASMA CENTERS FIRST QUARTER FY99



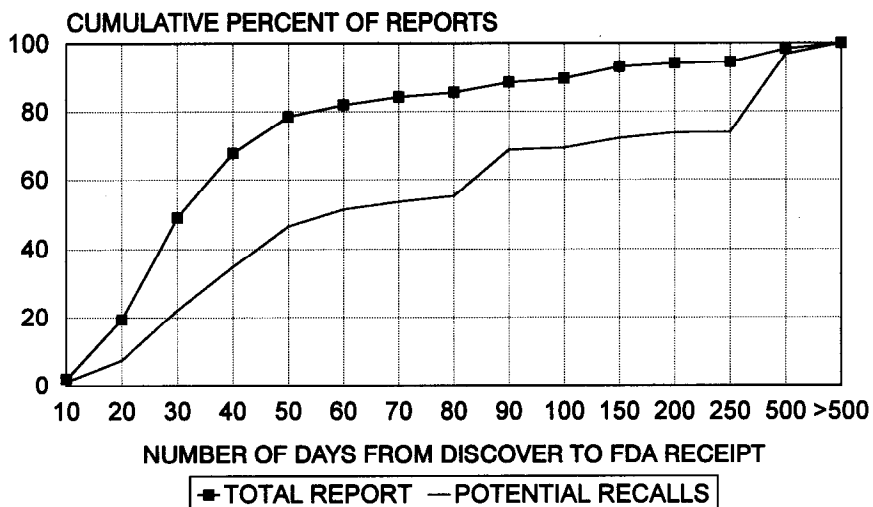
TOTAL REPORTS = 251
POTENTIAL RECALLS = 20

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



TOTAL REPORTS = 3392
POTENTIAL RECALLS = 487

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



TOTAL REPORTS = 3115
POTENTIAL RECALLS = 465