

DATE: **AUG - 2 1999**

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

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

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

Between April 1, 1999 and June 30, 1999, the Division of Inspections and Surveillance received 1,570 error and accident reports from the American Red Cross (ARC), 1,641 error and accident reports from non-ARC licensed blood establishments, 25 error and accident reports from unlicensed registered blood establishments, 11 reports from transfusion services, 597 error and accident reports from plasma centers, 15 reports from blood derivative manufacturers, 3 reports from an in-vitro diagnostic manufacturers, 4 reports from vaccine manufacturers, 6 reports from allergenics manufacturers, and 3 reports from therapeutic manufacturers. A total of 3,875 error and accident reports were received. There were 300 (7.7%) 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, 168 (4.3%) 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 June 30, 1999, the Division of Inspections and Surveillance received a total of 11,574 error and accident reports. There were 1,407 (12.2%) 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, 558 (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.

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
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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

THIRD QUARTER - FY99
ALL REPORTING ESTABLISHMENTS

	TOTAL REPORTS RECEIVED		POTENTIAL RECALLS	
	THIRD QUARTER	YEAR-TO-DATE	THIRD QUARTER	YEAR-TO-DATE
AMERICAN RED CROSS	1570	4868	105	339
NON-ARC LICENSED BLOOD BANKS	1641	5104	147	916
UNLICENSED BLOOD BANKS	25	109	2	15
TRANSFUSION SERVICES	11	23	0	0
PLASMA CENTERS	597	1401	38	119
BLOOD DERIVATIVE MANUFACTURER	15	29	5	6
IN-VITRO DIAGNOSTIC MANUFACTURER	3	13	0	4
VACCINE MANUFACTURER	4	7	0	1
ALLERGENICS MANUFACTURER	6	10	3	4
THERAPEUTIC MANUFACTURER	3	10	0	3
TOTAL	3875		300	
TOTAL - YEAR-TO-DATE 10/1/98 - 6/30/99		11574		1407

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

**THIRD 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	25	48	3	1	0	77	2.0%
VIRAL TESTING	7	11	0	0	1	19	0.5%
COLLECTION	19	11	0	0	1	31	0.8%
COMPONENT PREPARATION	17	27	2	0	0	46	1.2%
LABELING	127	132	3	3	1	266	6.9%
DONOR SCREENING	53	113	0	0	44	210	5.5%
DONOR DEFERRAL	10	8	0	0	2	20	0.5%
POST DONATION INFO	1179	1090	4	0	522	2795	72.7%
STORAGE/DISTRIBUTION	110	175	10	7	23	325	8.5%
MISCELLANEOUS	23	26	3	0	3	55	1.4%
TOTAL	1570	1641	25	11	597	3844	100%

POTENTIAL RECALLS

TYPE OF ERROR/ACCIDENT	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
ROUTINE TESTING	1	0	0	0	0	1	0.3%
VIRAL TESTING	3	5	0	0	1	9	3.1%
COLLECTION	4	3	0	0	1	8	2.7%
COMPONENT PREPARATION	11	11	0	0	0	22	7.5%
LABELING	11	16	0	0	0	27	9.2%
DONOR SCREENING	33	70	0	0	18	121	41.4%
DONOR DEFERRAL	5	8	0	0	2	15	5.1%
POST DONATION INFO	18	4	0	0	3	25	8.6%
STORAGE/DISTRIBUTION	19	30	2	0	13	64	21.9%
MISCELLANEOUS	0	0	0	0	0	0	0.0%
TOTAL	105	147	2	0	38	292	100%

THIRD 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	2	0	0	0	0	0	0	0	1	0	3	9.7%	0	0.0%
LABELING	1	1	2	0	3	3	1	0	0	0	7	22.6%	4	50.0%
STORAGE/DISTRIBUTION	0	0	1	0	1	0	0	0	0	0	2	6.5%	0	0.0%
MISCELLANEOUS	11	4	0	0	2	0	2	0	3	0	18	58.1%	4	50.0%
NOT REPORTABLE	1	0	0	0	0	0	0	0	0	0	1	3.2%	0	0.0%
TOTAL	15	5	3	0	6	3	3	0	4	0	31	100%	8	100%

YEAR-TO-DATE - FY99
NON-BLOOD MAUFACTURERS

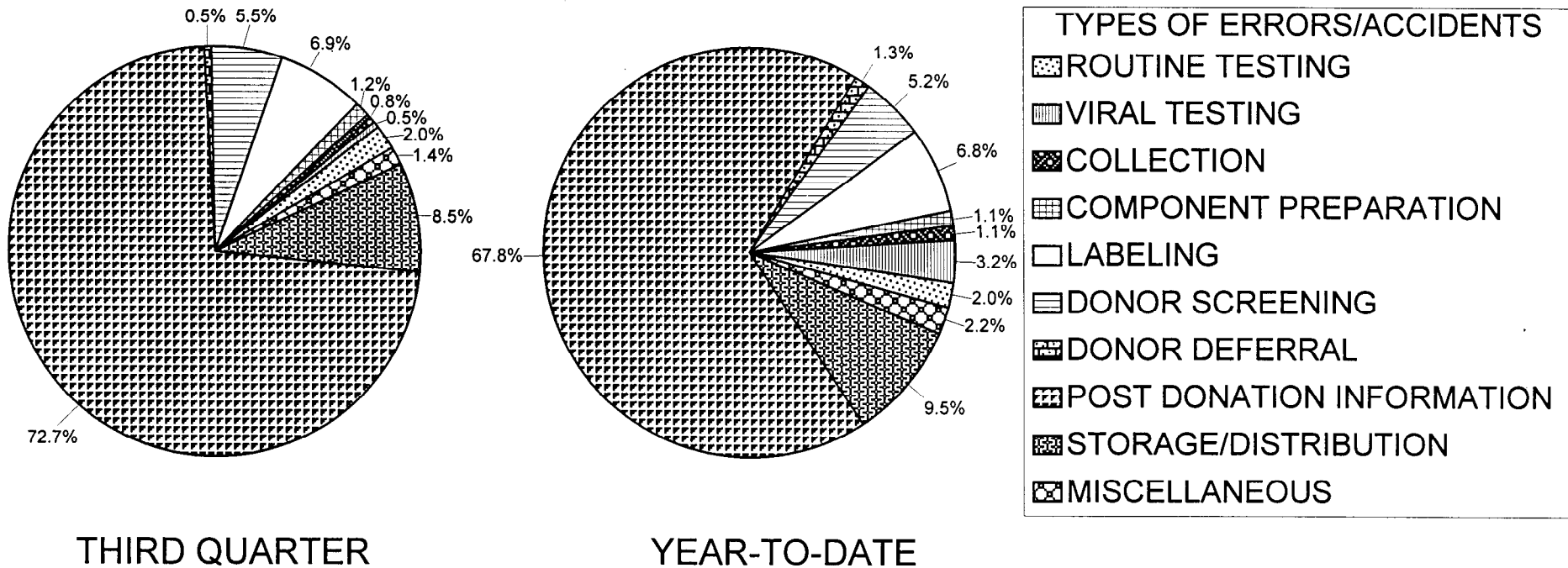
TYPE OF ERROR/ACCIDENT	DERIVATITVE		IN-VITRO DIAGNOSTIC		ALLERGENIC		THERAPUETIC		VACCINE		TOTAL REPORTS		POTENTIAL RECALL	
	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL				
REAGENT PERFORMANCE	0	0	1	1	0	0	0	0	0	0	1	1.4%	1	5.6%
STERILITY COMPROMISED	3	0	2	1	1	0	3	3	1	0	10	14.5%	4	22.2%
LABELING	2	1	7	2	6	4	1	0	0	0	16	23.2%	7	38.9%
STORAGE/DISTRIBUTION	2	0	1	0	1	0	1	0	1	0	6	8.7%	0	0.0%
MISCELLANEOUS	21	5	1	0	2	0	5	0	4	1	33	47.8%	6	33.3%
NOT REPORTABLE	0	0	1	0	0	0	0	0	1	0	3	4.3%	0	0.0%
TOTAL	28	6	13	4	10	4	10	3	7	1	69	100%	18	100%

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

TOTAL REPORTS

FY99



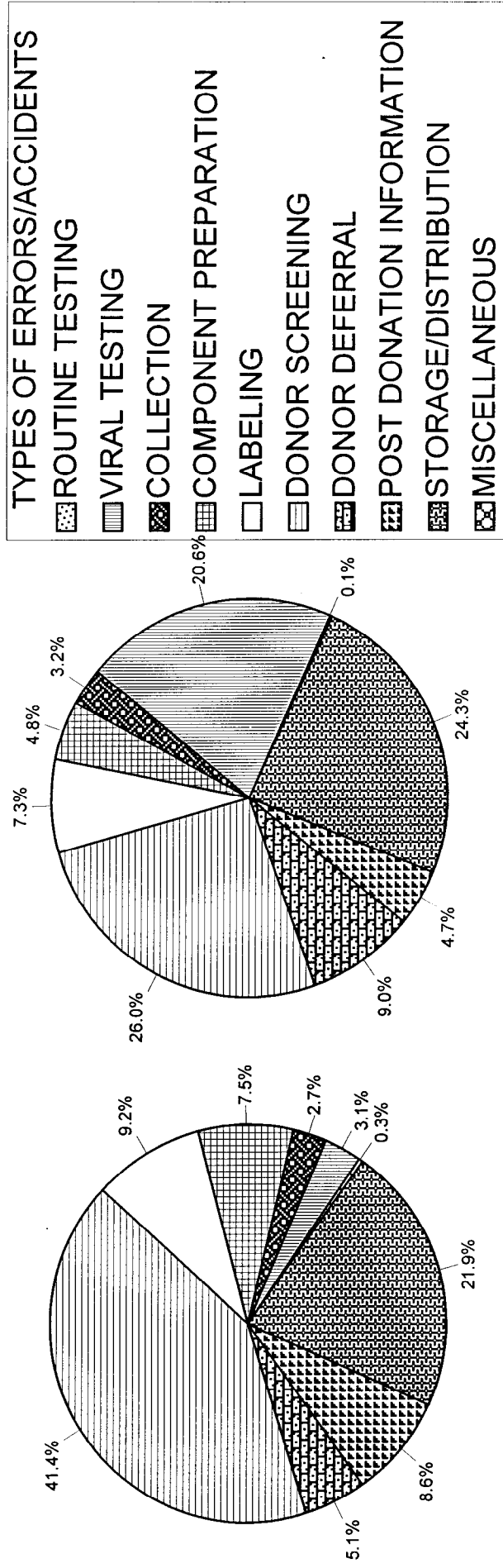
REPORTS RECEIVED THIRD QUARTER (4/1/99 - 6/30/99) = 3844

REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 6/30/99) = 11,505

ERROR AND ACCIDENT REPORTS ALL BLOOD AND PLASMA ESTABLISHMENTS

POTENTIAL RECALLS

FY99



THIRD QUARTER

YEAR-TO-DATE

REPORTS RECEIVED THIRD QUARTER (4/1/99 - 6/30/99) = 292
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 6/30/99) = 1389

THIRD QUARTER - FY99
BLOOD AND PLASMA ESTABLISHMENTS

TYPE OF ERROR/ACCIDENT	NON-REPORTABLE	REPORTABLE	TOTAL	%NON-REPORTABLE
ROUTINE TESTING	0	77	77	0.0%
VIRAL TESTING	0	19	19	0.0%
COLLECTION	9	22	31	29.0%
COMPONENT PREPARATION	0	46	46	0.0%
LABELING	42	224	266	15.8%
DONOR SCREENING	21	189	210	10.0%
DONOR DEFERRAL	2	18	20	10.0%
POST DONATION INFORMATION	27	2768	2795	1.0%
STORAGE/DISTRIBUTION	15	310	325	4.6%
MISCELLANEOUS	51	4	55	92.7%
TOTAL	167	3677	3844	4.3%

%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	223	225	0.9%
VIRAL TESTING	10	353	363	2.8%
COLLECTION	29	101	130	22.3%
COMPONENT PREPARATION	2	129	131	1.5%
LABELING	121	662	783	15.5%
DONOR SCREENING	49	544	593	8.3%
DONOR DEFERRAL	5	139	144	3.5%
POST DONATION INFO	53	7742	7795	0.7%
STORAGE/DISTRIBUTION	50	1042	1092	4.6%
MISCELLANEOUS	234	15	249	94.0%
TOTAL	555	10950	11505	4.8%

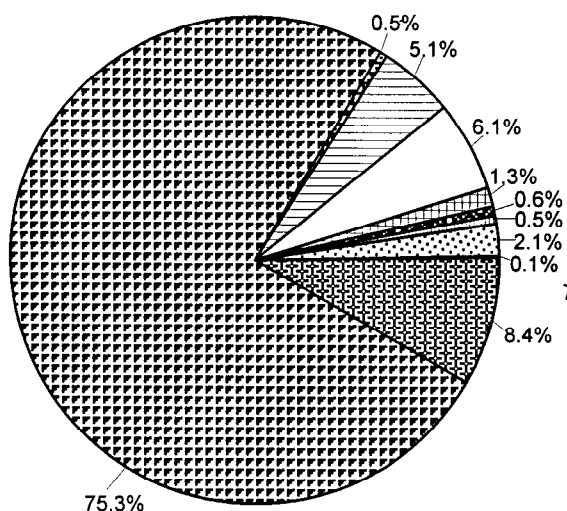
%NON-REPORTABLE = Non-Reportable/Total for each category

ERROR AND ACCIDENT REPORTS

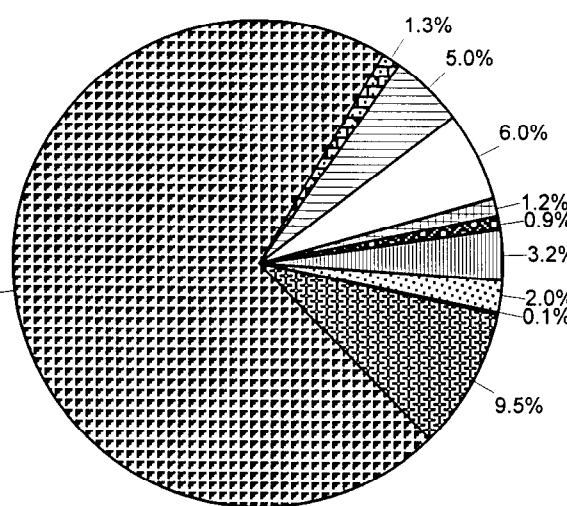
ALL BLOOD AND PLASMA ESTABLISHMENTS

REPORTABLE ERRORS/ACCIDENTS

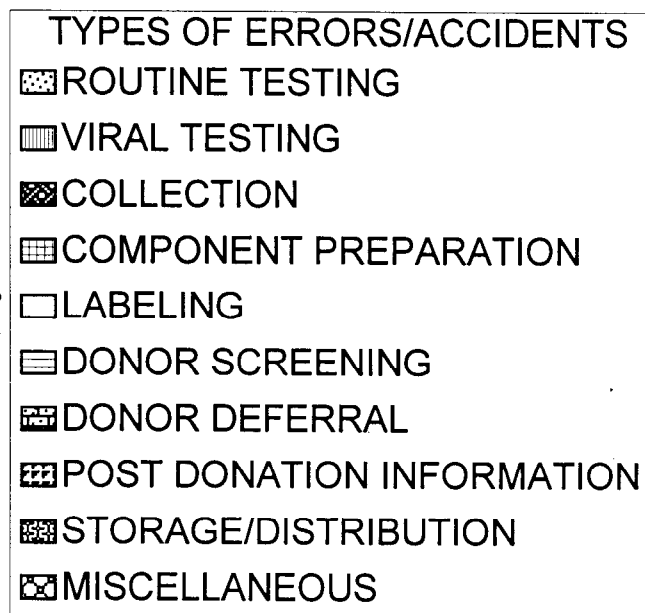
FY99



THIRD QUARTER



YEAR-TO-DATE



REPORTS RECEIVED THIRD QUARTER (4/1/99 - 6/30/99) = 3677
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 6/30/99) = 10,950

FY99 YEAR-TO-DATE

REPORTABLE ERRORS/ACCIDENTS – 10,950 (95.2% of total reports)

Top Three Categories of Errors/Accidents:

Post Donation Information - 7742 (70.7% 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 – 1042 (9.5% 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 – 662 (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

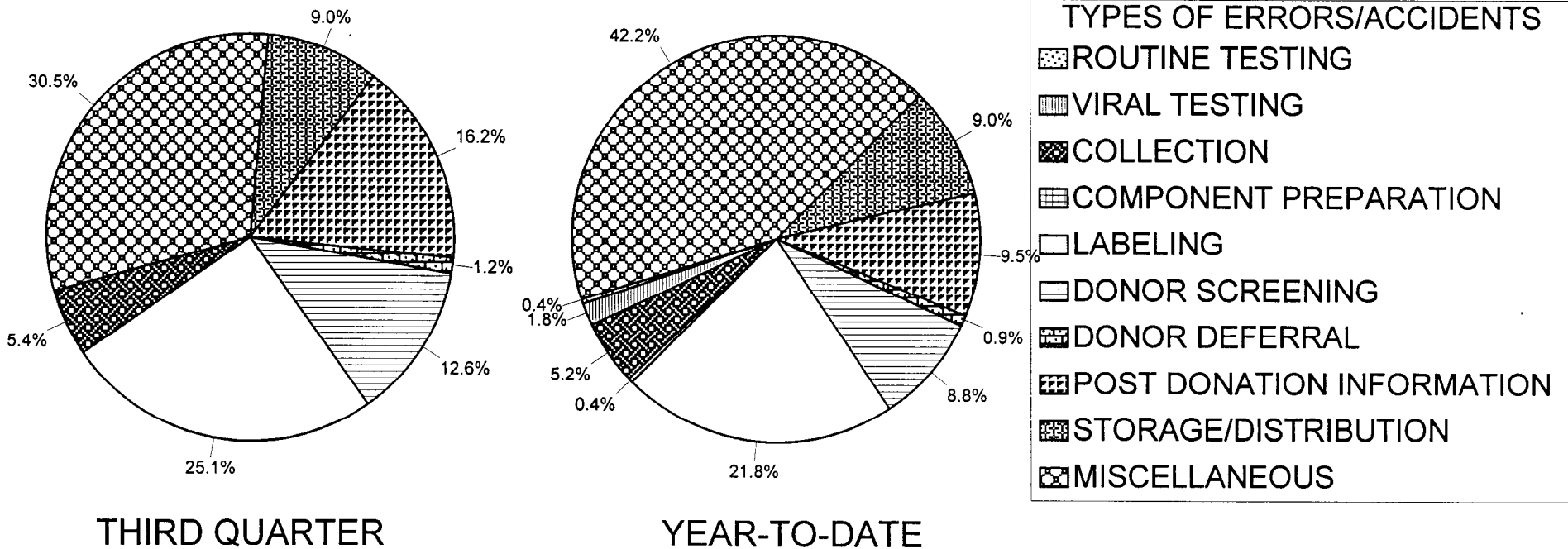
*Examples of errors and accidents represent at least 50% of reports in each category.

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

NON-REPORTABLE ERRORS/ACCIDENTS

FY99



REPORTS RECEIVED THIRD QUARTER (4/1/99 - 6/30/99) = 167

REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 6/30/99) = 555

FY99 YEAR-TO-DATE

NON-REPORTABLE ERRORS/ACCIDENTS - 555 (4.8% of total reports)

Top Three Categories of Errors/Accidents:

Miscellaneous 234 (42.2% of non-reportables)

**Examples:*

- No products made available for distribution
- Notification/retrieval procedures not followed (e.g., notification not performed within appropriate time)
- Routine quality control (e.g., QC for scale, centrifuge, temperatures) not performed or inadequate, does not include product, viral marker, or ABO/Rh QC

Labeling - 121 (21.8% 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

Post Donation Information (9.5% of non-reportables)

**Example:*

- Post donation cold/flu symptoms
- Donor pregnant

*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
THIRD 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	15	7	12	14
25%	21	21	15	16	21
50%	28	34	33	28	30
75%	38	71	93	50	47
90%	48	160	127	97	97
# REPORTS	1477	1581	33	579	3670
RANGE	1-264	5-2385	1-237	4-3301	1-3301

**ERROR AND ACCIDENT REPORTS
RECEIVED 10/1/98 - 6/30/99**

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

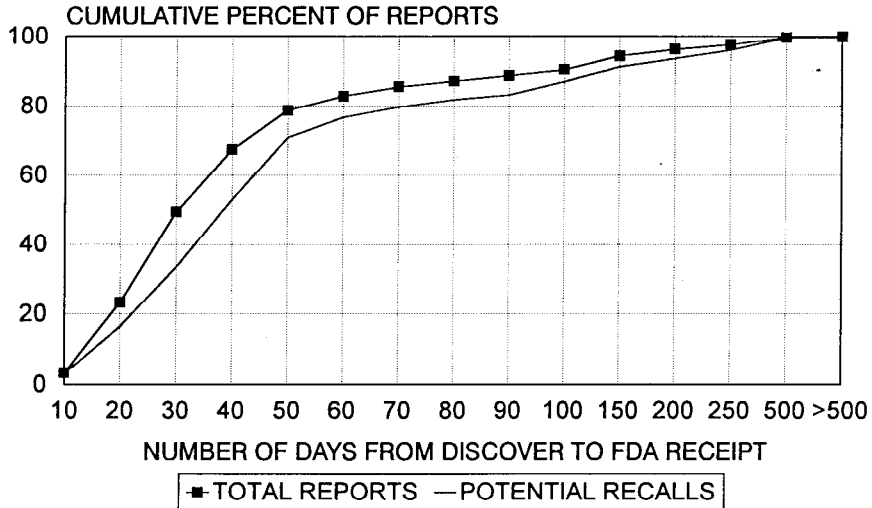
CUMULATIVE PERCENT OF REPORTS	ARC (DAYS)	NON-ARC LICENSED (DAYS)	UNLICENSED (DAYS)	PLASMA (DAYS)	TOTAL (DAYS)
10%	16	15	7	12	14
25%	21	22	14	16	21
50%	28	36	32	28	31
75%	38	86	80	53	48
90%	47	316	197	123	117
# REPORTS	4580	4891	97	1364	10932
RANGE	1-383	3-2385	1-831	4-3301	1-3301

ERROR AND ACCIDENT REPORTS

REPORTING TIME

ALL REPORTING BLOOD ESTABLISHMENTS

THIRD QUARTER FY99



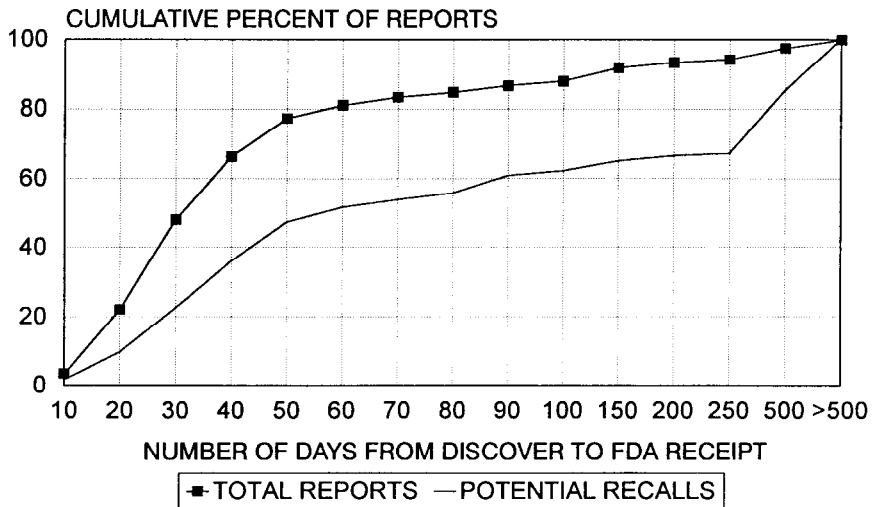
TOTAL REPORTS = 3670
 POTENTIAL RECALLS = 287

ERROR AND ACCIDENT REPORTS

REPORTING TIME

ALL REPORTING BLOOD ESTABLISHMENTS

YEAR -TO-DATE FY99



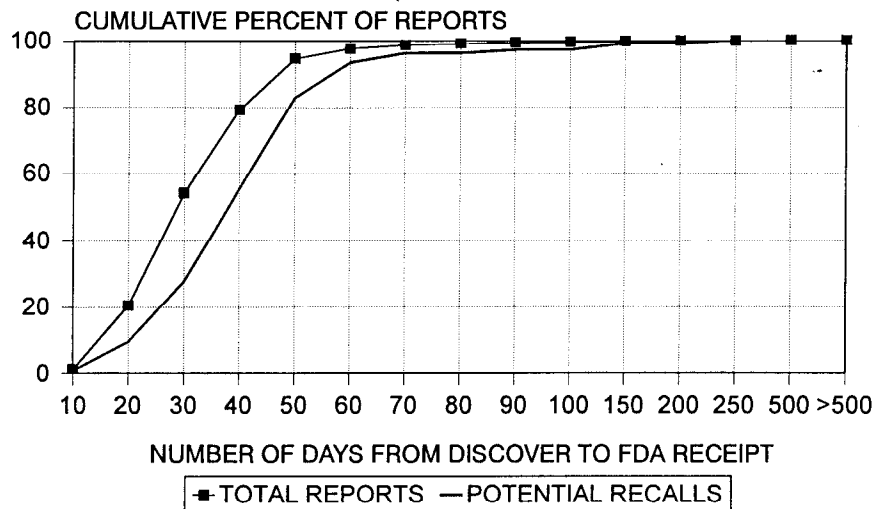
TOTAL REPORTS = 10,932
 POTENTIAL RECALLS = 1381

ERROR AND ACCIDENT REPORTS

REPORTING TIME

AMERICAN RED CROSS

THIRD QUARTER FY99



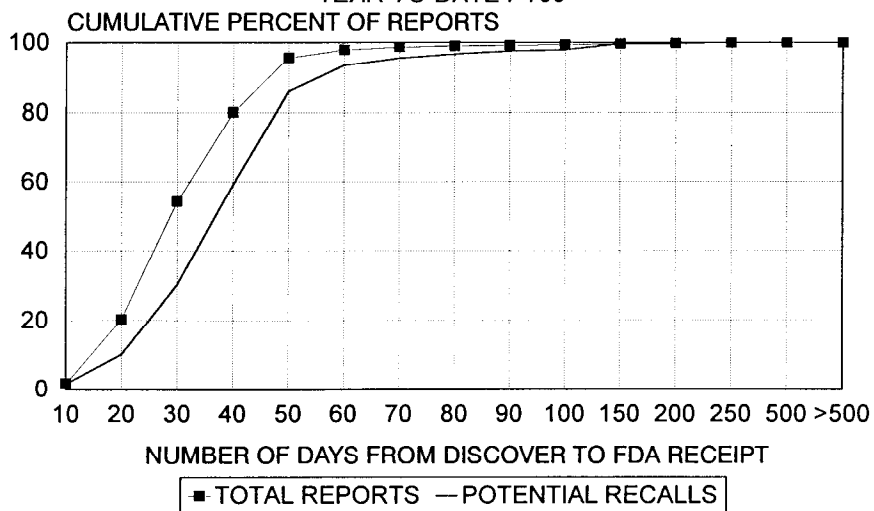
TOTAL REPORTS = 1477
 POTENTIAL RECALLS = 105

ERROR AND ACCIDENT REPORTS

REPORTING TIME

AMERICAN RED CROSS

YEAR-TO-DATE FY99

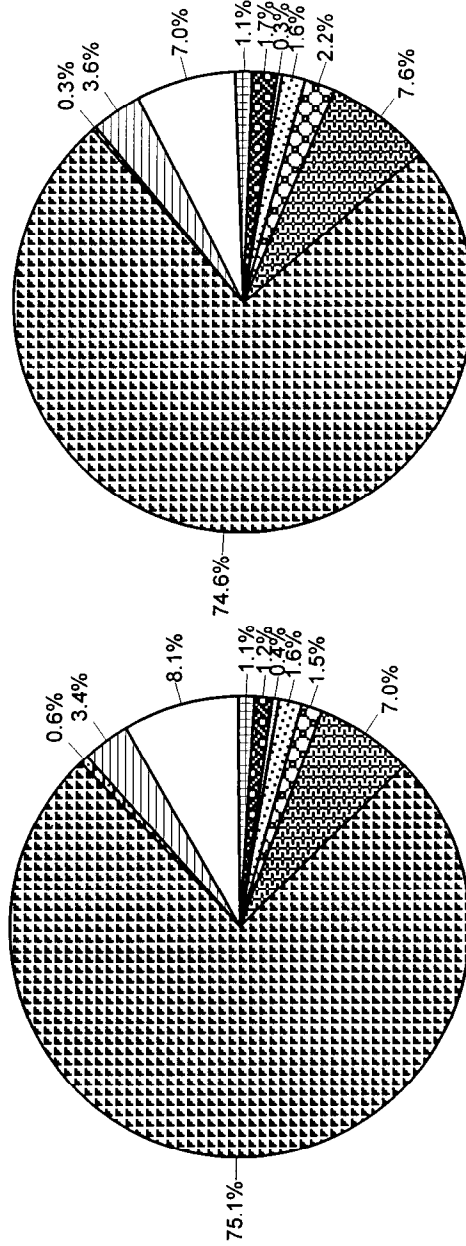
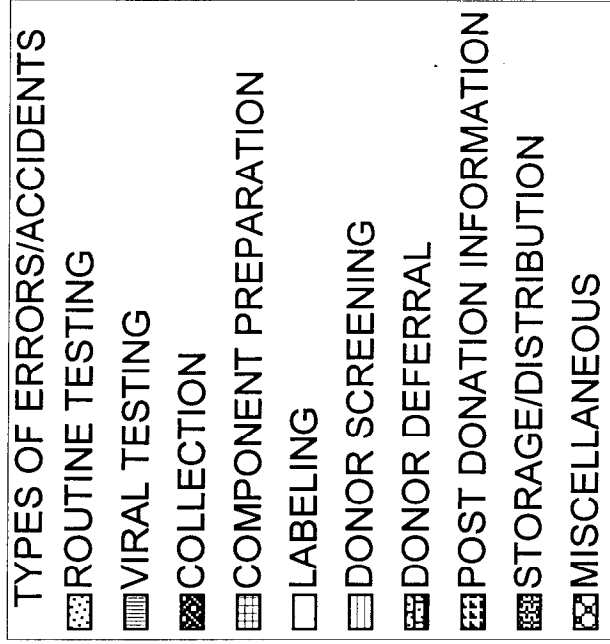


TOTAL REPORTS = 4580
 POTENTIAL RECALLS = 339

ERROR AND ACCIDENT REPORTS

AMERICAN RED CROSS

FY99



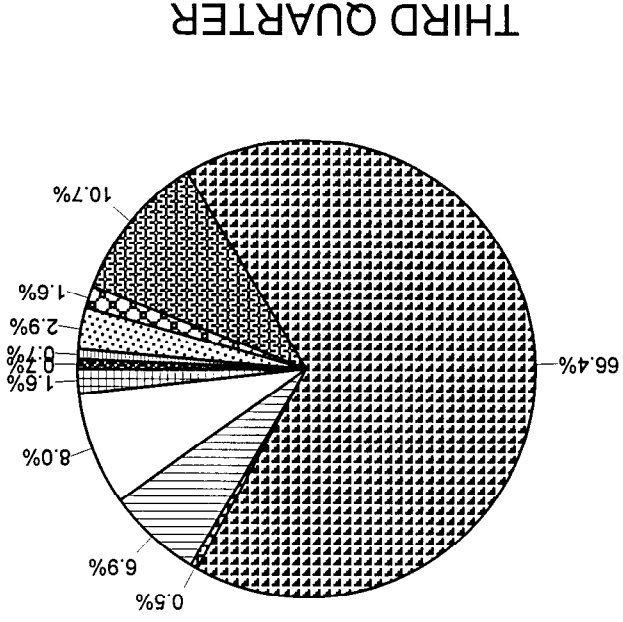
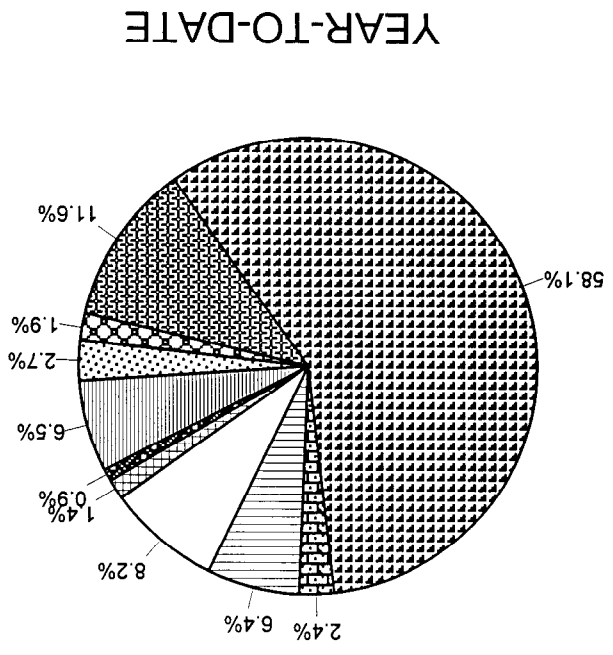
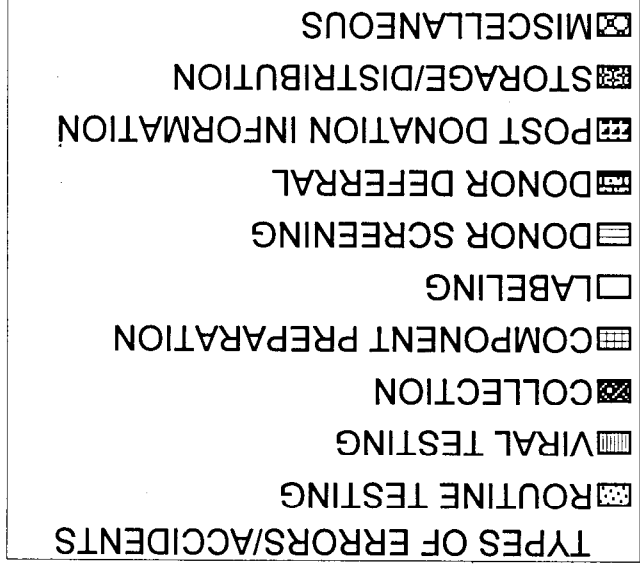
THIRD QUARTER

YEAR-TO-DATE

REPORTS RECEIVED THIRD QUARTER (4/1/99 - 6/30/99) = 1570
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 6/30/99) = 4868

ERROR AND ACCIDENT REPORTS NON-ARC LICENSED BLOOD BANKS

FY99

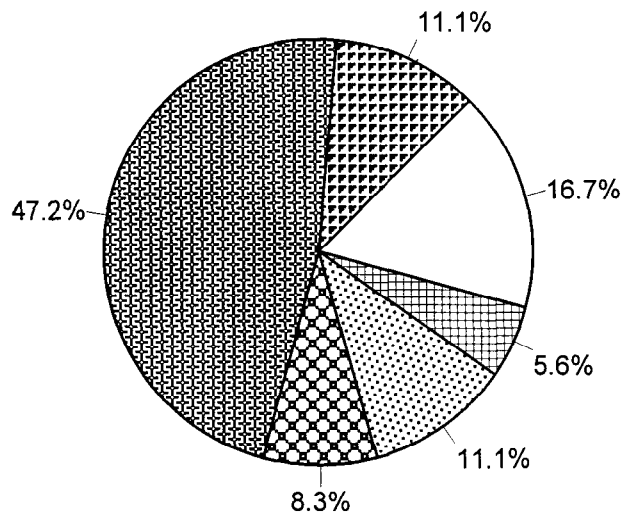


REPORTS RECEIVED THIRD QUARTER (4/1/99 - 6/30/99) = 1641
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 6/30/99) = 5104

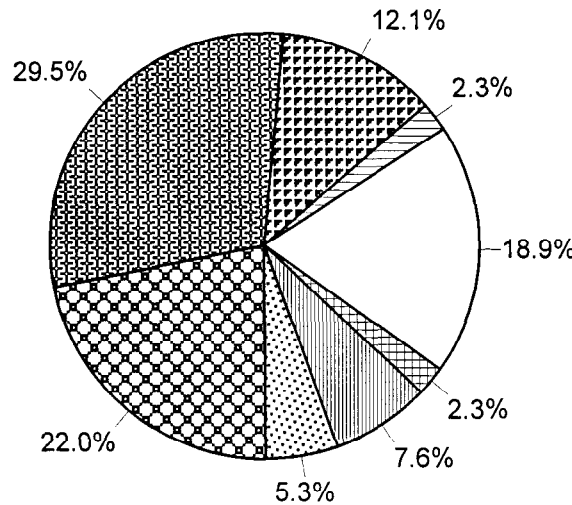
ERROR AND ACCIDENT REPORTS

UNLICENSED BLOOD BANKS

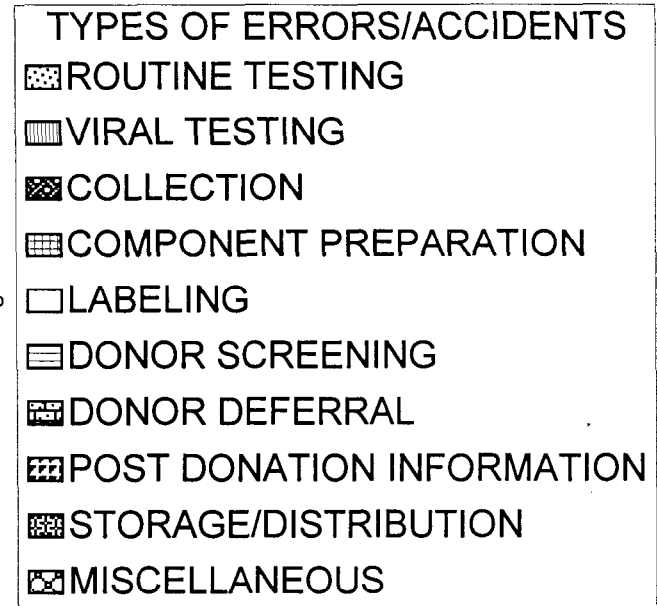
FY99



THIRD QUARTER



YEAR-TO-DATE

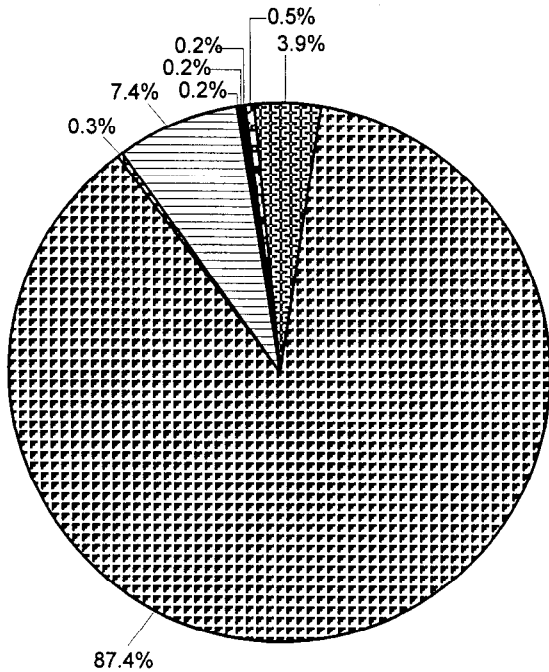


REPORTS RECEIVED THIRD QUARTER (4/1/99 - 6/30/99) = 36 (11 REPORTS - TRANSFUSION SERVICES)
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 6/30/99) = 132 (23 REPORTS - TRANSFUSION SERVICES)

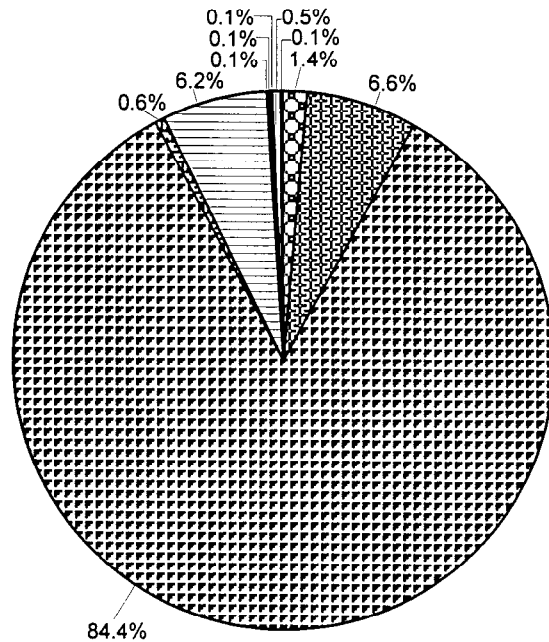
ERROR AND ACCIDENT REPORTS

PLASMA CENTERS

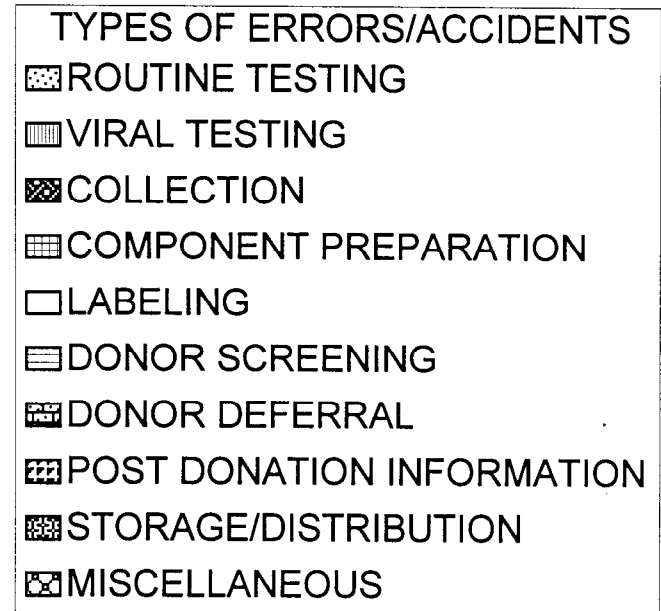
FY99



THIRD QUARTER



YEAR-TO-DATE

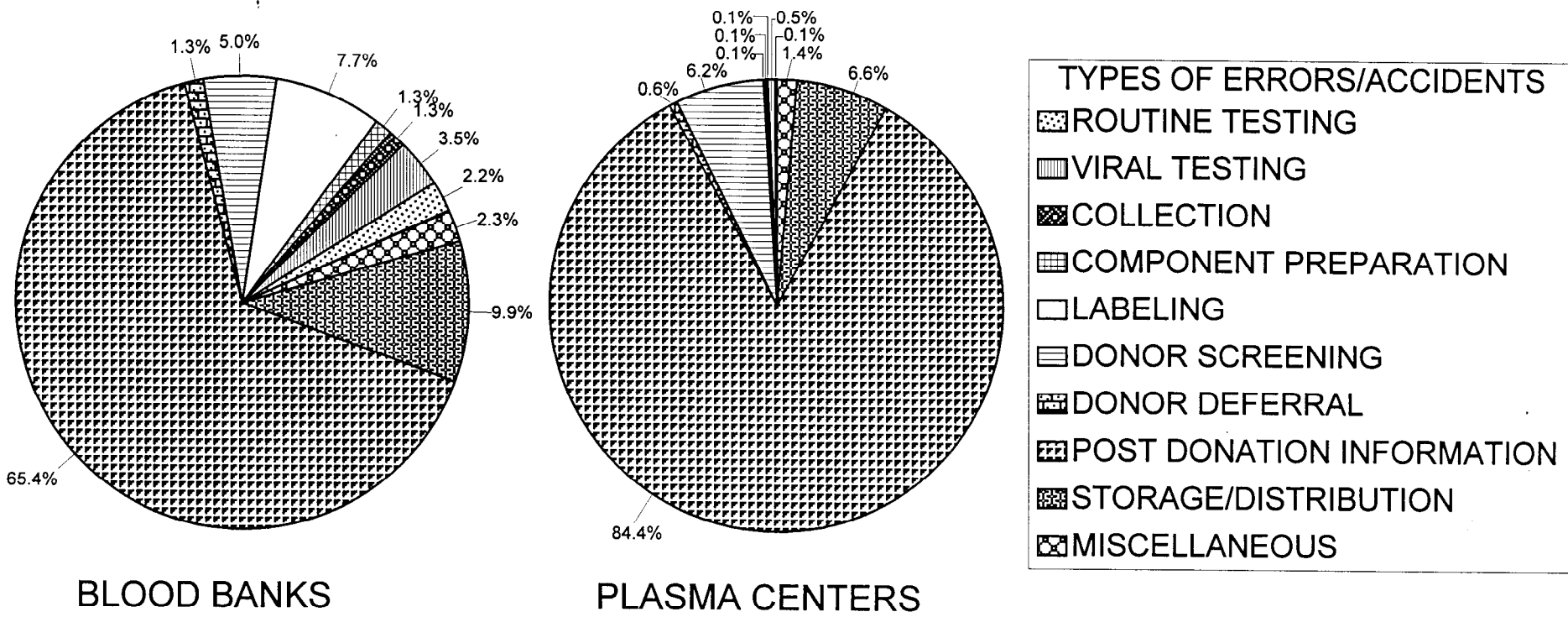


REPORTS RECEIVED THIRD QUARTER (4/1/99 - 6/30/99) = 597
 REPORTS RECEIVED YEAR-TO-DATE (10/1/98 - 6/30/99) = 1401

ERROR AND ACCIDENT REPORTS

BLOOD BANKS VERSUS PLASMA CENTERS

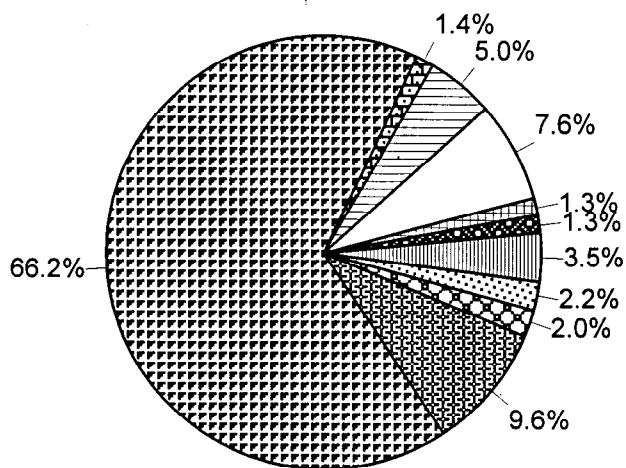
FY99 YEAR-TO-DATE



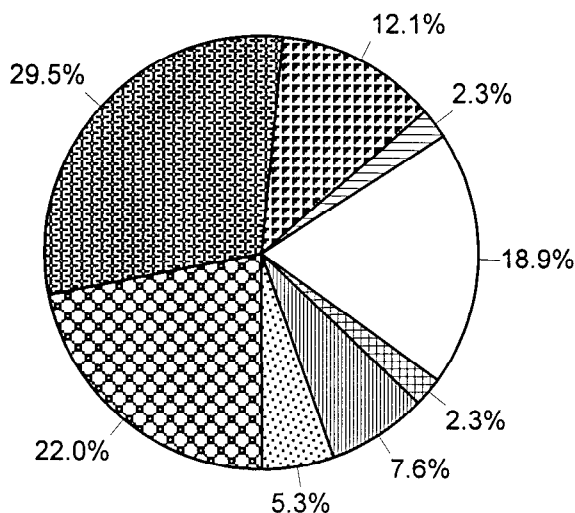
REPORTS RECEIVED 10/1/98 - 6/30/99
 BLOOD BANKS = 10,104
 PLASMA CENTERS = 1401

ERROR AND ACCIDENT REPORTS BLOOD BANKS VERSUS PLASMA CENTERS

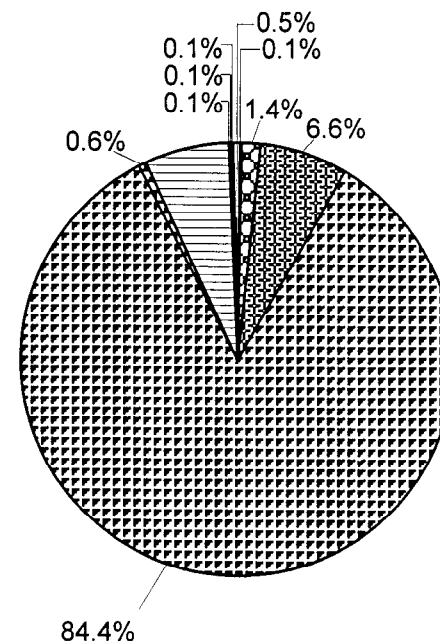
FY99 YEAR-TO-DATE



LICENSED
BLOOD BANKS



UNLICENSED
BLOOD BANKS



PLASMA
CENTERS

TYPES OF ERRORS/ACCIDENTS

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

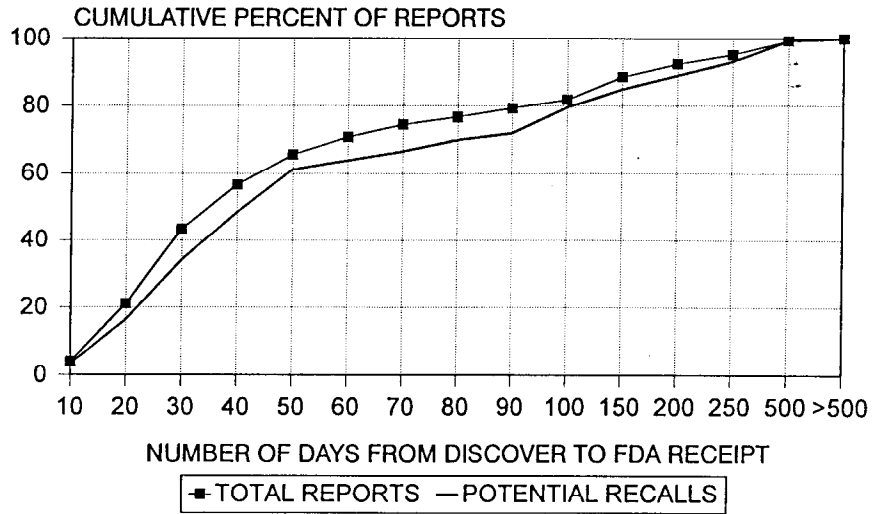
REPORTS RECEIVED 10/1/98 - 6/30/99

LICENSED BLOOD BANKS = 9972

UNLICENSED BLOOD BANKS = 132

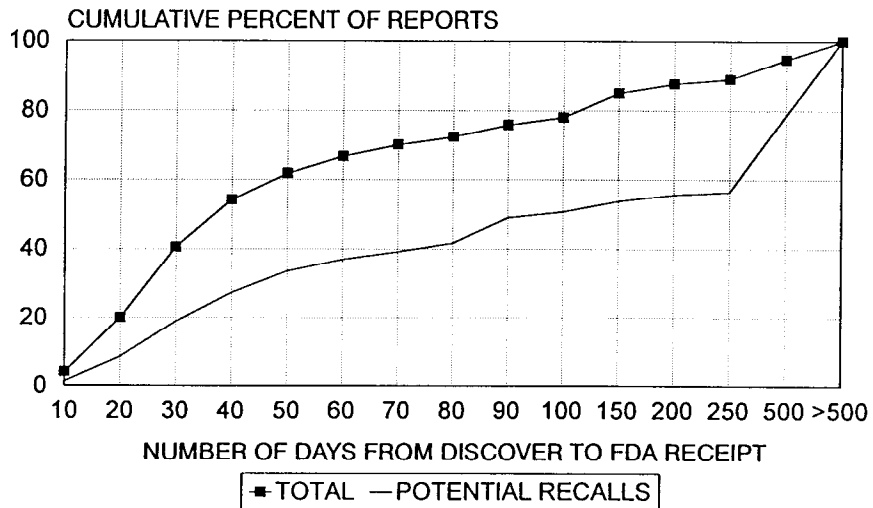
PLASMA CENTERS = 1401

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



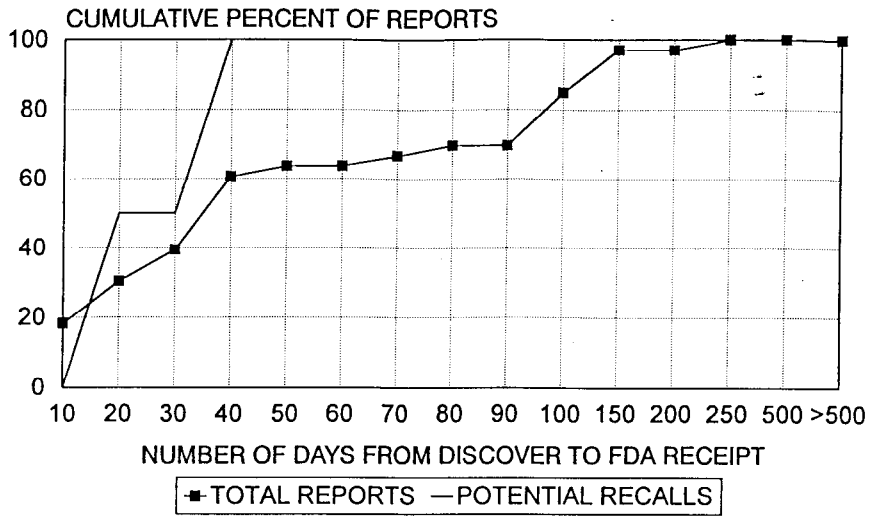
TOTAL REPORTS = 1581
POTENTIAL RECALLS = 147

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



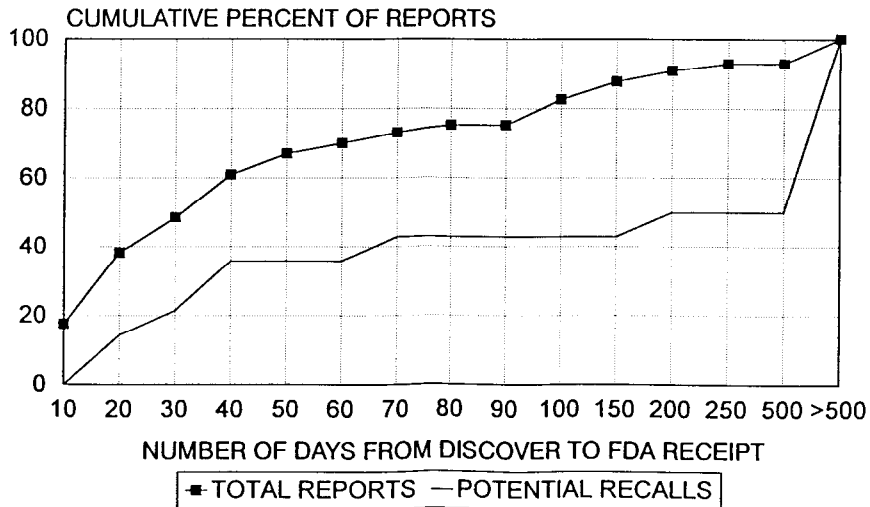
TOTAL REPORTS = 4891
POTENTIAL RECALLS = 914

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



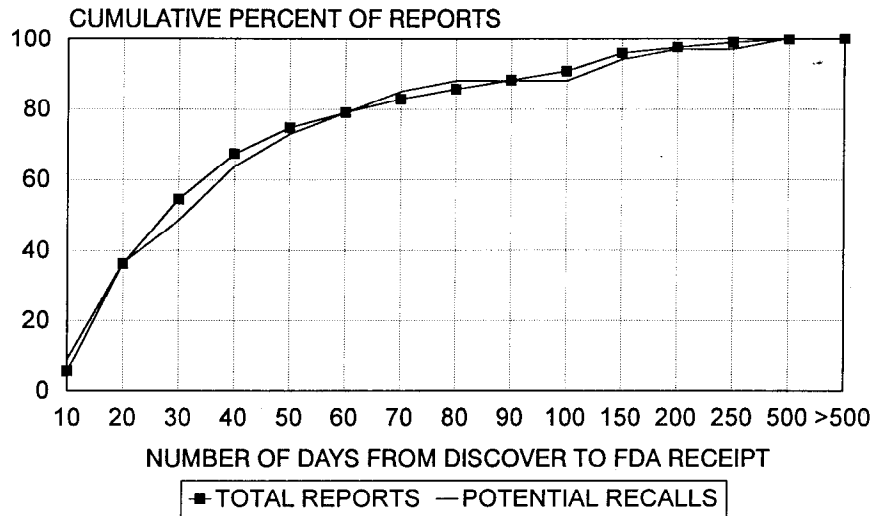
TOTAL REPORTS = 33
POTENTIAL RECALLS = 2

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



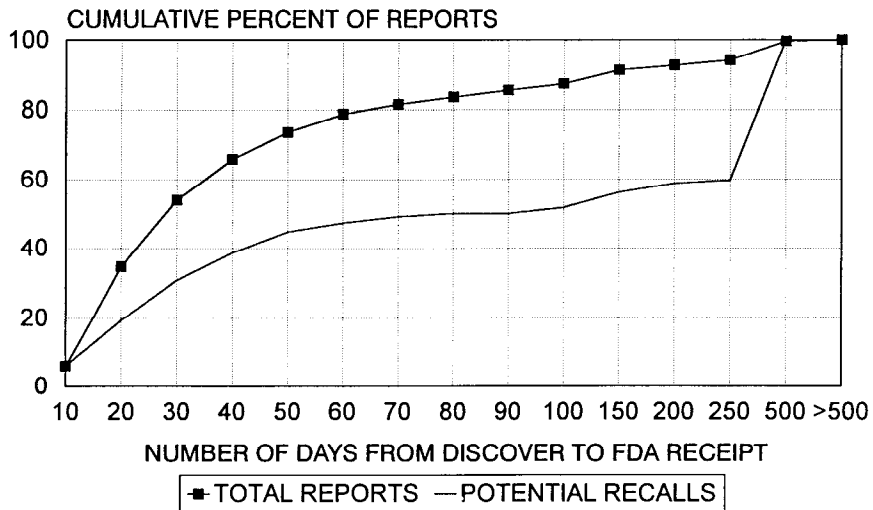
TOTAL REPORTS = 97
POTENTIAL RECALLS = 14

ERROR AND ACCIDENT REPORTS REPORTING TIME PLASMA CENTERS THIRD QUARTER FY99



TOTAL REPORTS = 579
POTENTIAL RECALLS = 33

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



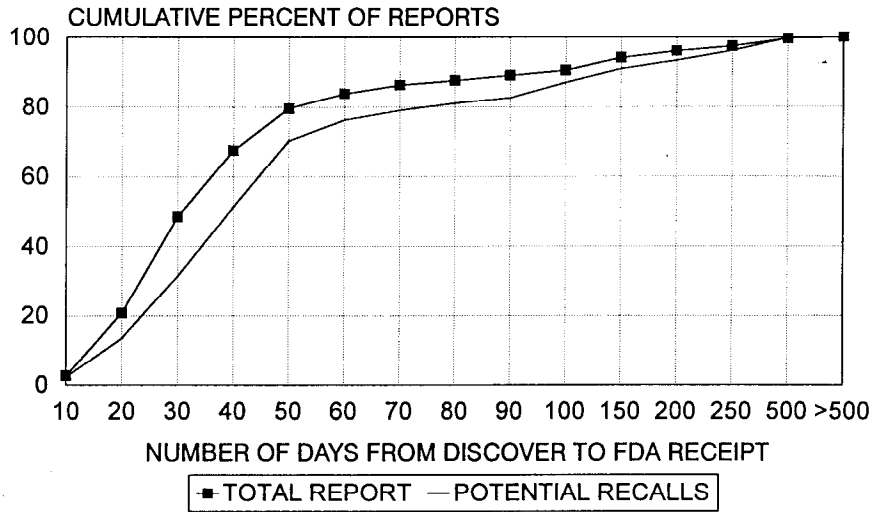
TOTAL REPORTS = 1364
POTENTIAL RECALLS = 114

ERROR AND ACCIDENT REPORTS

REPORTING TIME

ALL LICENSED BLOOD BANKS

THIRD QUARTER FY99



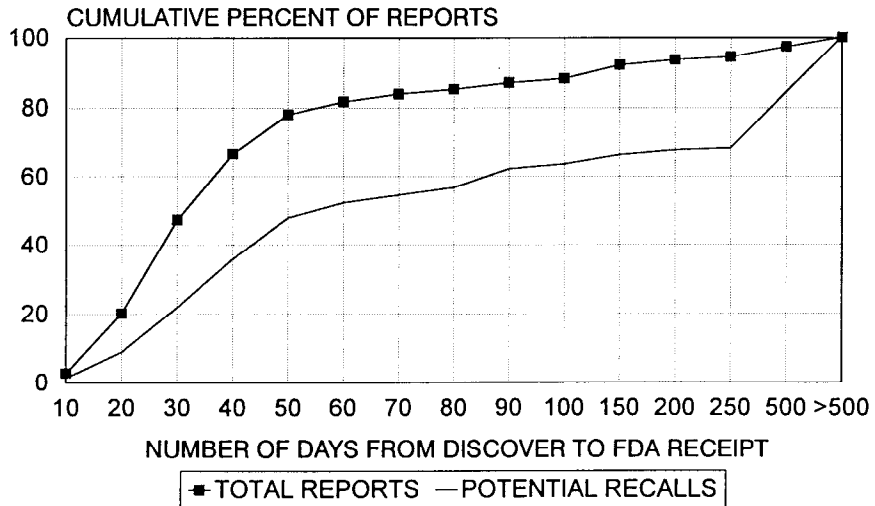
TOTAL REPORTS = 3058
 POTENTIAL RECALLS = 252

ERROR AND ACCIDENT REPORTS

REPORTING TIME

ALL LICENSED BLOOD BANKS

YEAR-TO-DATE FY99



TOTAL REPORTS = 9471
 POTENTIAL RECALLS = 1253