

MEMORANDUM

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

DATE: MAY 14 1998

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

SUBJECT: Error and Accident Reports - Summary for Second Quarter FY98

TO: Director, Division of Inspections and Surveillance (HFM-650) *Byrd Jopke* 5/14/98

Between January 1, 1998 and March 31, 1998, the Division of Inspections and Surveillance received 1,339 error and accident reports from the American Red Cross (ARC), 1,483 error and accident reports from non-ARC licensed blood establishments, 50 error and accident reports from unlicensed registered blood establishments, 324 error and accident reports from plasma centers, 4 reports from transfusion services, 1 report from an in-vitro diagnostic manufacturer, 1 report from a vaccine manufacturer, and 2 reports from therapeutic manufacturers. A total of 3,204 error and accident reports were received. There were 404 (12.6%) 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, 200 (6.2%) 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, 1997 and March 31, 1998, the Division of Inspections and Surveillance received a total of 6,359 error and accident reports. There were 788 (12.4%) 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, 449 (7.1%) 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

- 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
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Plasma Centers
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All Licensed Blood Establishments

SECOND QUARTER - FY98
ALL REPORTING ESTABLISHMENTS

	TOTAL REPORTS RECEIVED		POTENTIAL RECALLS	
	SECOND QUARTER	YEAR-TO-DATE	SECOND QUARTER	YEAR-TO-DATE
AMERICAN RED CROSS	1339	2858	134	289
NON-ARC LICENSED BLOOD BANKS	1483	2839	238	440
UNLICENSED BLOOD BANKS	50	78	3	6
TRANSFUSION SERVICES	4	10	0	0
PLASMA CENTERS	324	563	28	50
BLOOD DERIVATIVE MANUFACTURER	0	3	0	0
IN-VITRO DIAGNOSTIC MANUFACTURER	1	4	1	3
VACCINE MANUFACTURER	1	2	0	0
ALLERGENICS MANUFACTURER	0	0	0	0
THERAPEUTICS MANUFACTURER	2	2	0	0
TOTAL	3204		404	
TOTAL - YEAR-TO-DATE 10/1/97 - 3/31/98		6359		788

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

**SECOND QUARTER - FY98
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	35	75	5	1	0	116	3.6%
VIRAL TESTING	11	37	1	0	3	52	1.6%
COLLECTION	18	14	1	0	0	33	1.0%
COMPONENT PREPARATION	37	49	3	0	0	89	2.8%
LABELING	147	175	5	0	1	328	10.3%
DONOR SCREENING	63	136	2	0	13	214	6.7%
DONOR DEFERRAL	6	13	0	0	4	23	0.7%
POST DONATION INFO	843	811	8	0	268	1930	60.3%
STORAGE/DISTRIBUTION	142	150	12	2	23	329	10.3%
MISCELLANEOUS	37	23	13	1	12	86	2.7%
TOTAL	1339	1483	50	4	324	3200	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	0.5%
VIRAL TESTING	7	31	0	0	1	39	9.7%
COLLECTION	6	5	0	0	0	11	2.7%
COMPONENT PREPARATION	24	36	0	0	0	60	14.9%
LABELING	17	30	1	0	0	48	11.9%
DONOR SCREENING	41	72	2	0	6	121	30.0%
DONOR DEFERRAL	6	11	0	0	4	21	5.2%
POST DONATION INFO	6	4	0	0	1	11	2.7%
STORAGE/DISTRIBUTION	27	47	0	0	16	90	22.3%
MISCELLANEOUS	0	0	0	0	0	0	0.0%
TOTAL	134	238	3	0	28	403	100%

SECOND QUARTER - FY98
NON-BLOOD MAUFACTURERS

TYPE OF ERROR/ACCIDENT	IN-VITRO DIAGNOSTIC		DERIVATIVE		VACCINE		THERAPEUTIC		TOTAL		RECALL	
	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL				
LABELING	0	0	0	0	1	0	0	0	1	25%	0	0%
DECREASE IN POTENCY	1	1	0	0	0	0	0	0	1	25%	1	100%
STORAGE AND DISTRIBUTION	0	0	0	0	0	0	1	0	1	25%	0	0%
STERILITY COMPROMISED	0	0	0	0	0	0	1	0	1	25%	0	0%
TOTAL	1	1	0	0	1	0	2	0	4	100%	1	100%

YEAR-TO-DATE - FY98
NON-BLOOD MAUFACTURERS

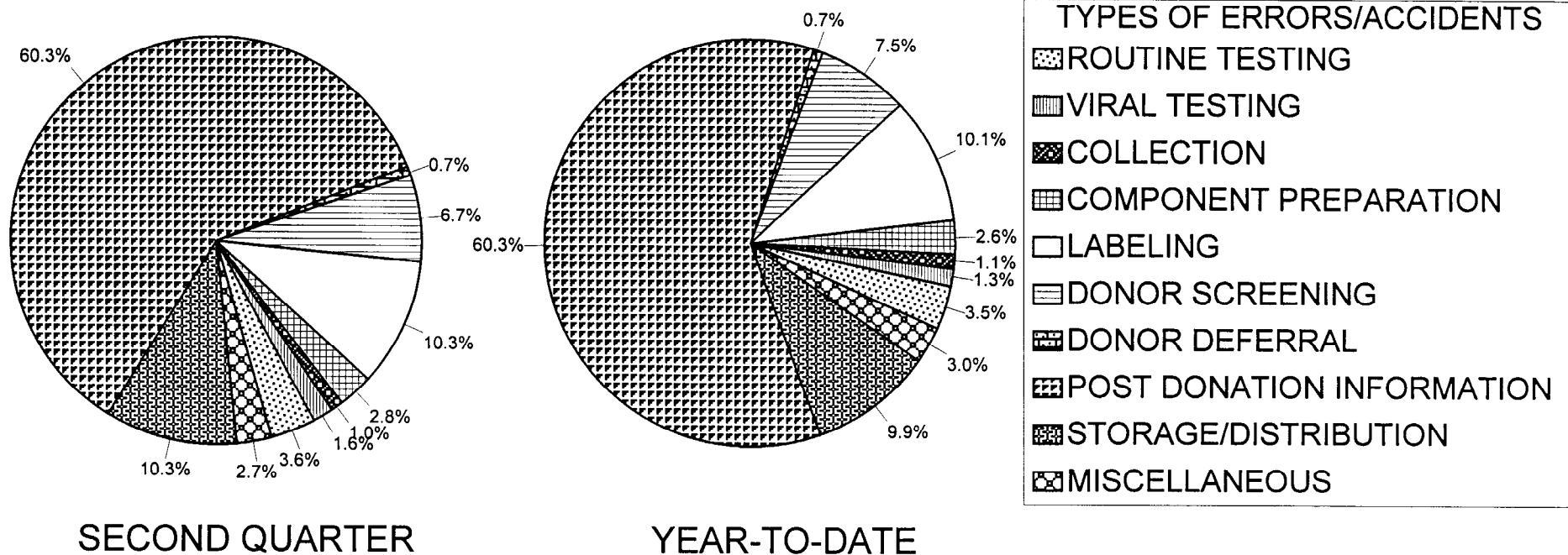
TYPE OF ERROR/ACCIDENT	IN-VITRO DIAGNOSTIC		DERIVATIVE		VACCINE		THERAPEUTIC		TOTAL		RECALL	
	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL				
LABELING	1	1	0	0	1	0	0	0	2	18.2%	1	33.3%
DECREASE IN POTENCY	2	2	0	0	0	0	0	0	2	18.2%	1	33.3%
STORAGE AND DISTRIBUTION	0	0	1	0	0	0	1	0	2	18.2%	0	0.0%
SOURCE MATERIAL WITHDRAWN DUE TO CJD RISK	0	0	1	0	0	0	0	0	1	9.1%	0	0.0%
STERILITY COMPROMISED - AIR CONTAMINATION	0	0	1	0	0	0	1	0	2	18.2%	0	0.0%
UNAPPROVED SEED PASSAGE USED	0	0	0	0	1	0	0	0	1	9.1%	1	33.3%
NON-REPORTABLE - PRODUCTS NOT MADE AVAILABLE	1	0	0	0	0	0	0	0	1	9.1%	0	0.0%
TOTAL	4	3	3	0	2	0	2	0	11	100%	3	100%

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

TOTAL REPORTS

FY98



REPORTS RECEIVED SECOND QUARTER (1/1/98 - 3/31/98) = 3200

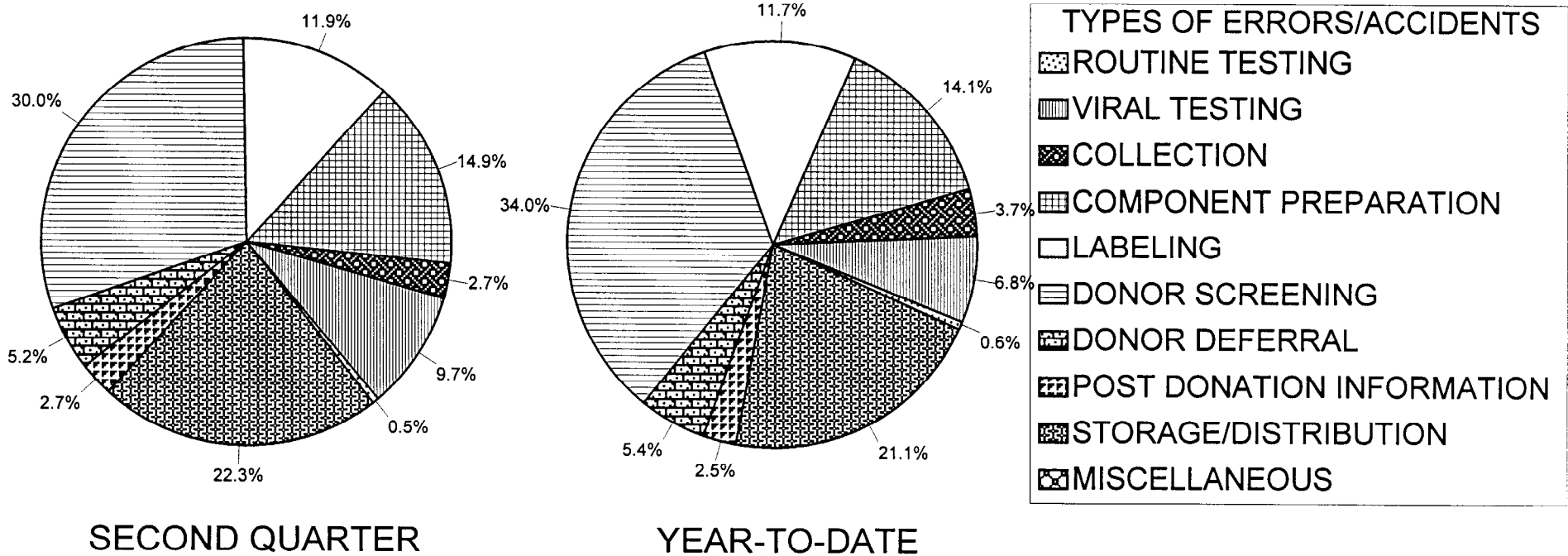
REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 3/31/98) = 6346

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

POTENTIAL RECALLS

FY98

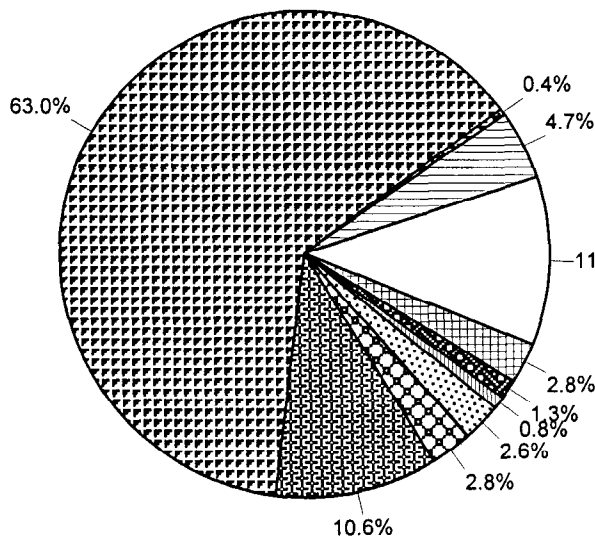


REPORTS RECEIVED SECOND QUARTER (1/1/98 - 3/31/98) = 403
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 3/31/98) = 785

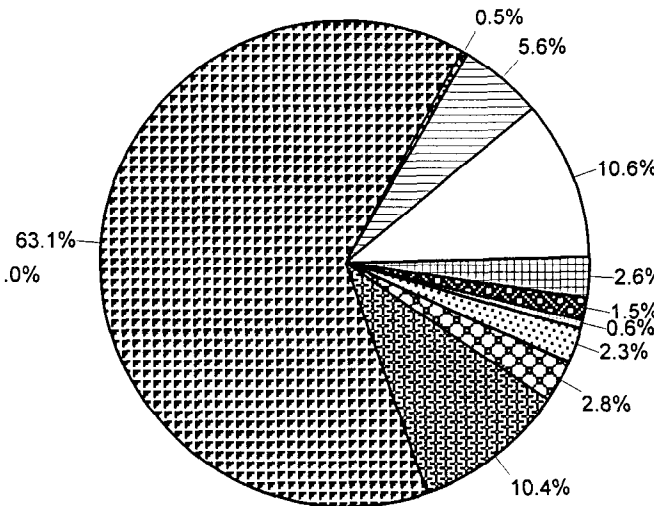
ERROR AND ACCIDENT REPORTS

AMERICAN RED CROSS

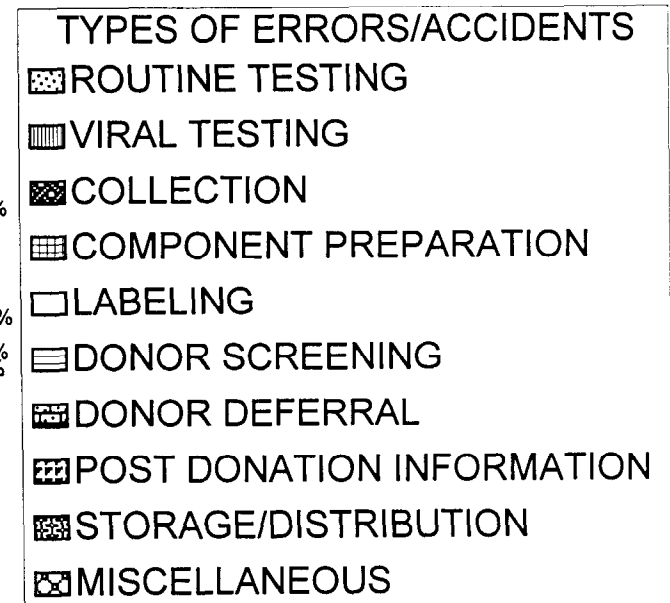
FY98



SECOND QUARTER



YEAR-TO-DATE

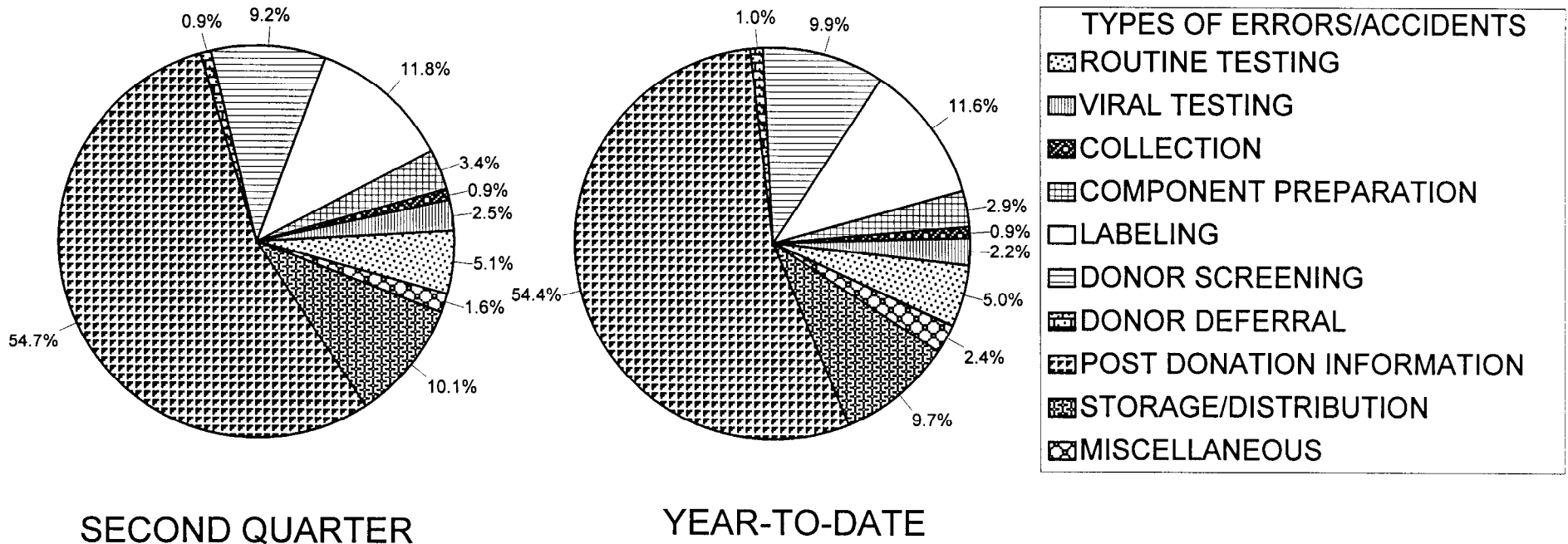


REPORTS RECEIVED SECOND QUARTER (1/1/98 - 3/31/98) = 1339
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 3/31/98) = 2858

ERROR AND ACCIDENT REPORTS

NON-ARC LICENSED BLOOD BANKS

FY98

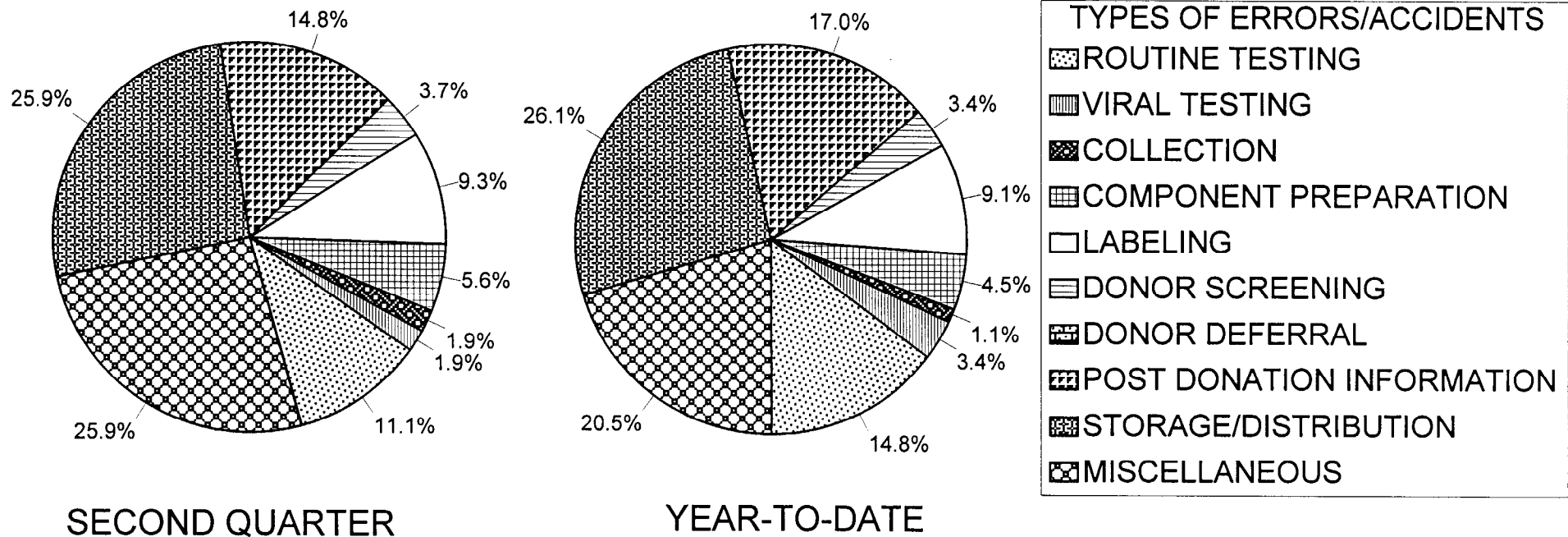


REPORTS RECEIVED SECOND QUARTER (1/1/98 - 3/31/98) = 1483
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 3/31/98) = 2837

ERROR AND ACCIDENT REPORTS

UNLICENSED BLOOD BANKS

FY98

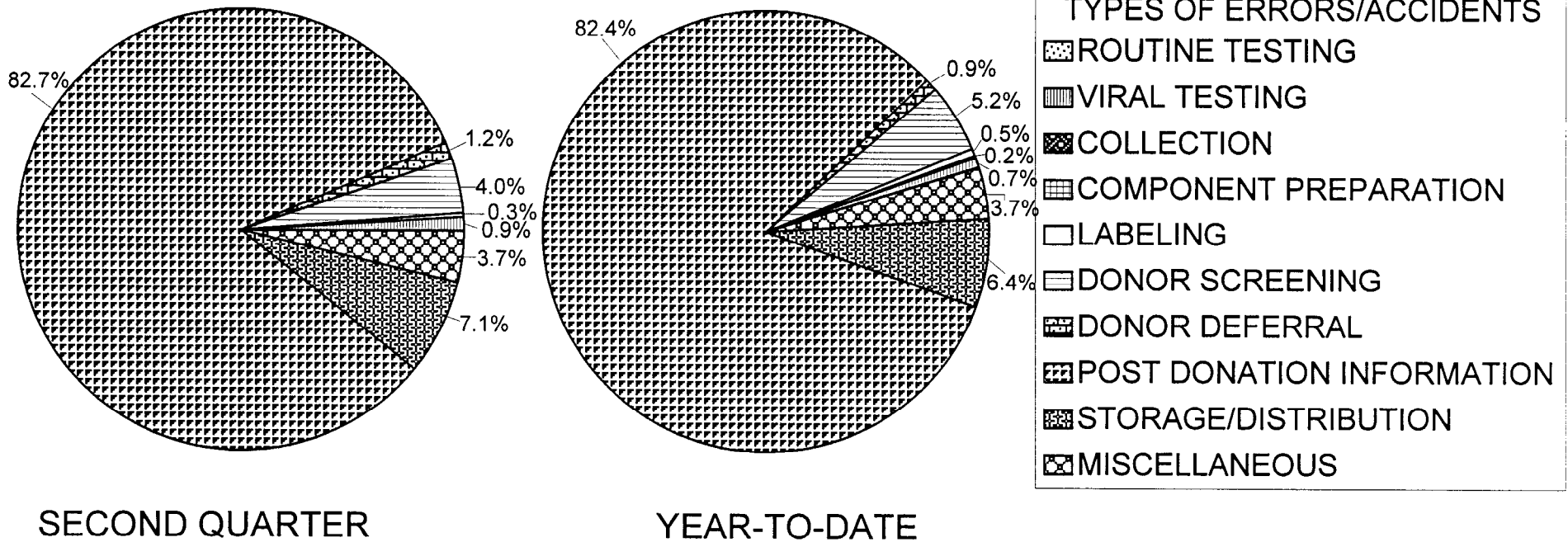


REPORTS RECEIVED SECOND QUARTER (1/1/98 - 3/31/98) = 54 (4 REPORTS - TRANSFUSION SERVICES)
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 3/31/98) = 88 (10 REPORTS - TRANSFUSION SERVICES)

ERROR AND ACCIDENT REPORTS

PLASMA CENTERS

FY98

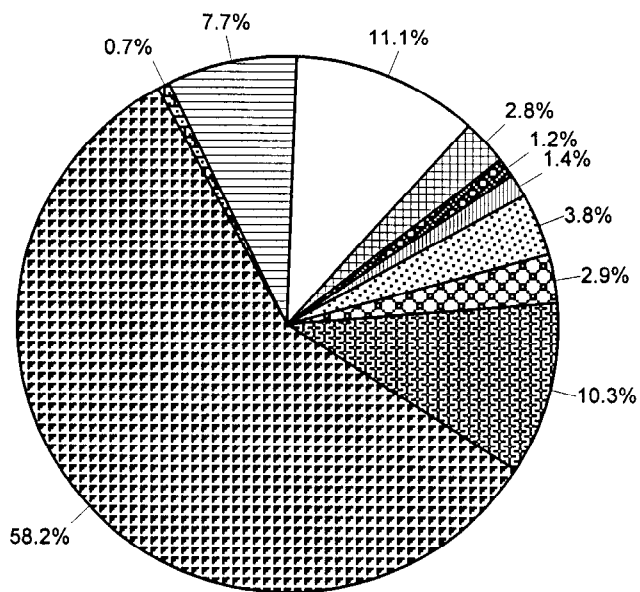


REPORTS RECEIVED SECOND QUARTER (1/1/98 - 3/31/98) = 324
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 3/31/98) = 563

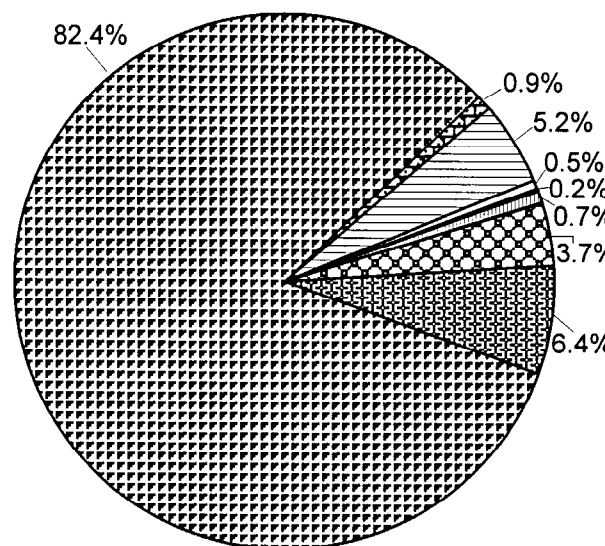
ERROR AND ACCIDENT REPORTS

BLOOD BANKS VERSUS PLASMA CENTERS

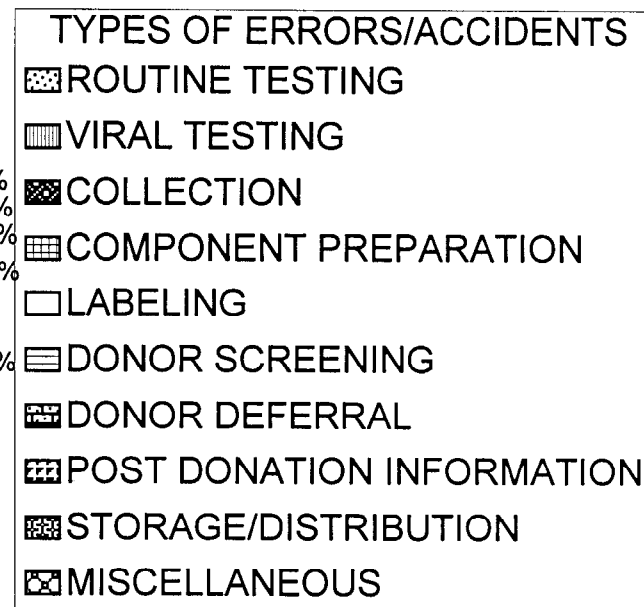
FY98 YEAR-TO-DATE



BLOOD BANKS

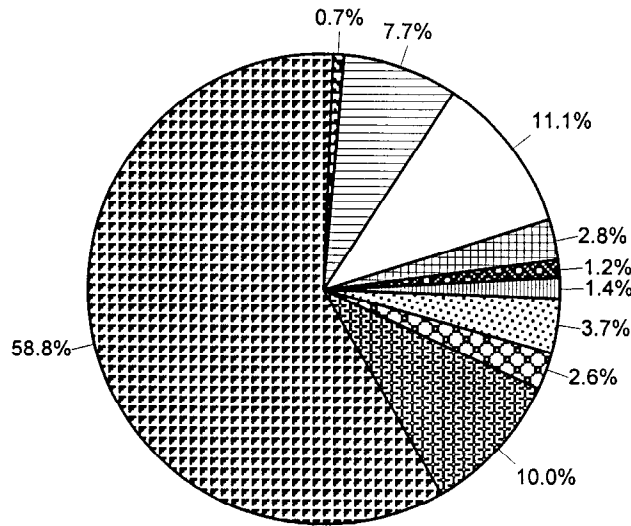


PLASMA CENTERS

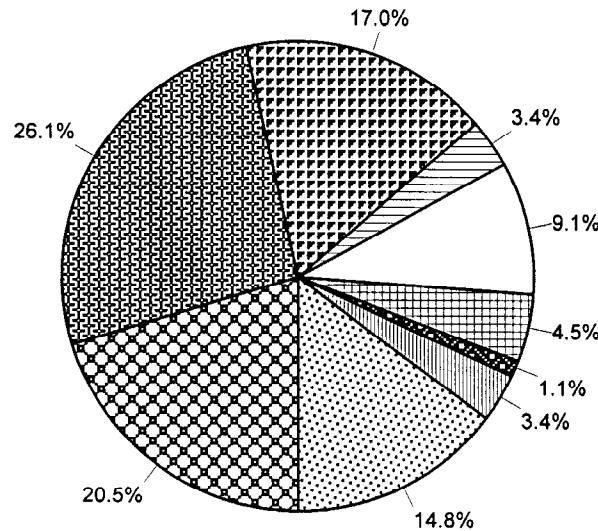


REPORTS RECEIVED 10/1/97 - 3/31/98
 BLOOD BANKS = 5783
 PLASMA CENTERS = 563

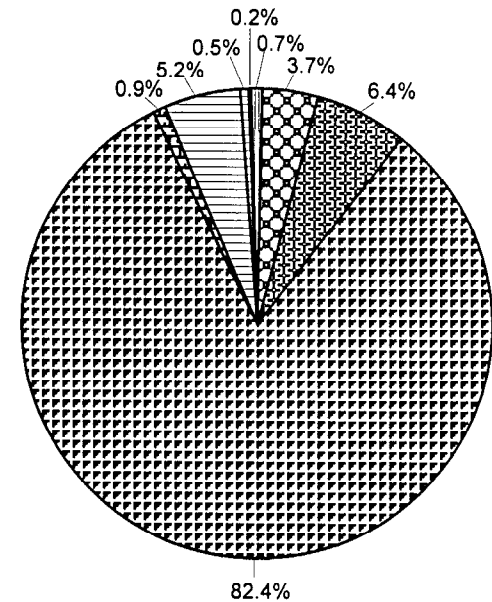
ERROR AND ACCIDENT REPORTS BLOOD BANKS VERSUS PLASMA CENTERS FY98 YEAR-TO-DATE



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
- STORAGE/DISTRIBUTION
- COLLECTION
- DONOR SCREENING

REPORTS RECEIVED 10/1/97 - 3/31/98
 LICENSED BLOOD BANKS = 5695
 UNLICENSED BLOOD BANKS = 88
 PLASMA CENTERS = 563

SECOND QUARTER - FY98
BLOOD AND PLASMA ESTABLISHMENTS

TYPE OF ERROR/ACCIDENT	NON-REPORTABLE	REPORTABLE	TOTAL	%NON-REPORTABLE
ROUTINE TESTING	0	116	116	0.0%
VIRAL TESTING	0	52	52	0.0%
COLLECTION	11	21	33	34.4%
COMPONENT PREPARATION	1	89	89	1.1%
LABELING	43	285	328	13.1%
DONOR SCREENING	23	191	214	10.7%
DONOR DEFERRAL	0	23	23	0.0%
POST DONATION INFORMATION	13	1917	1929	0.7%
STORAGE/DISTRIBUTION	29	300	329	8.8%
MISCELLANEOUS	80	6	86	93.0%
TOTAL	200	3000	3200	6.3%

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

FY98 - YEAR-TO-DATE
BLOOD AND PLASMA ESTABLISHMENTS

TYPE OF ERROR/ACCIDENT	NON-REPORTABLE	REPORTABLE	TOTAL	%NON-REPORTABLE
ROUTINE TESTING	0	221	221	0.0%
VIRAL TESTING	7	78	85	8.2%
COLLECTION	21	48	69	30.4%
COMPONENT PREPARATION	2	161	163	1.2%
LABELING	93	550	643	14.5%
DONOR SCREENING	56	417	473	11.8%
DONOR DEFERRAL	1	45	46	2.2%
POST DONATION INFORMATION	31	3798	3827	0.8%
STORAGE/DISTRIBUTION	66	565	631	10.5%
MISCELLANEOUS	172	16	188	91.5%
TOTAL	449	5899	6348	7.1%

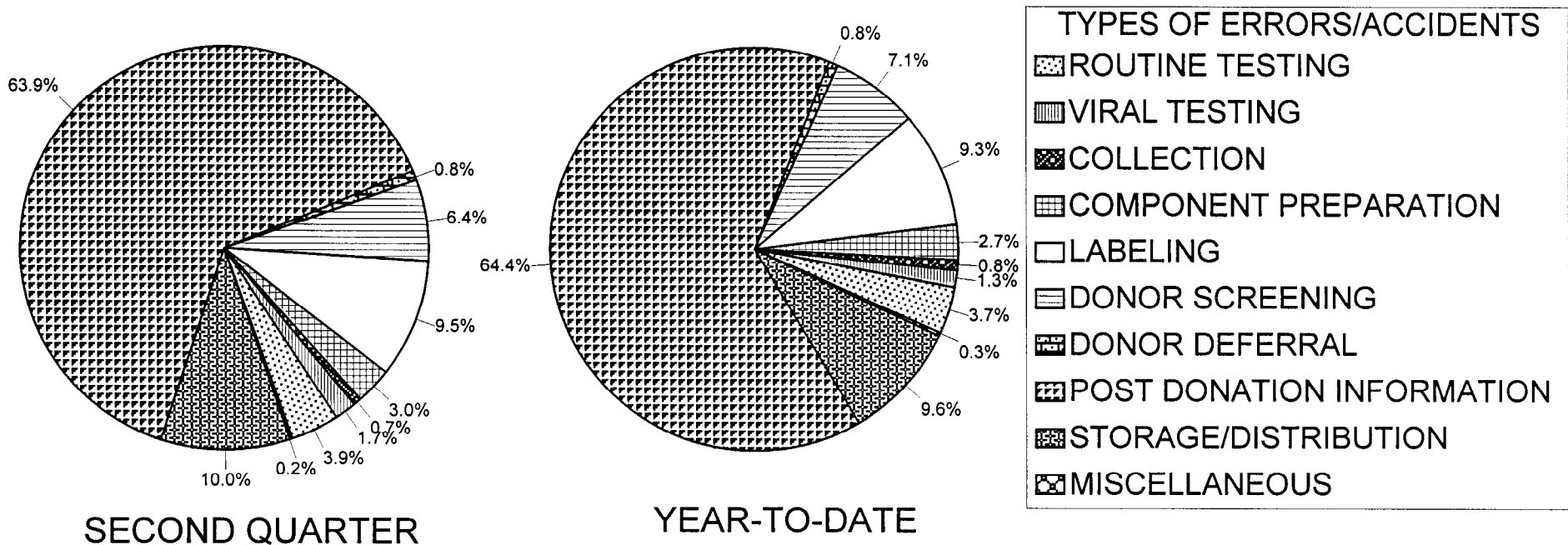
%NON-REPORTABLE = Non-Reportable/Total for each category

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

REPORTABLE ERRORS/ACCIDENTS

FY98



REPORTS RECEIVED SECOND QUARTER (1/1/98 - 3/31/98) = 3000
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 3/31/98) = 5899

FY98 YEAR-TO-DATE

REPORTABLE ERRORS/ACCIDENTS - 5899 (92.8% of total reports)

Top Three Categories of Errors/Accidents:

Post Donation Information - 3798 (64.4% of reportables)

**Examples:*

Information provided post donation:

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

Storage/Distribution - 565 (9.6% 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 unsuitable medical history
- Failure to quarantine a unit that was designated to be quarantined due to incorrect, incomplete, or positive testing

Labeling - 550 (9.3% 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
- Incorrect product label

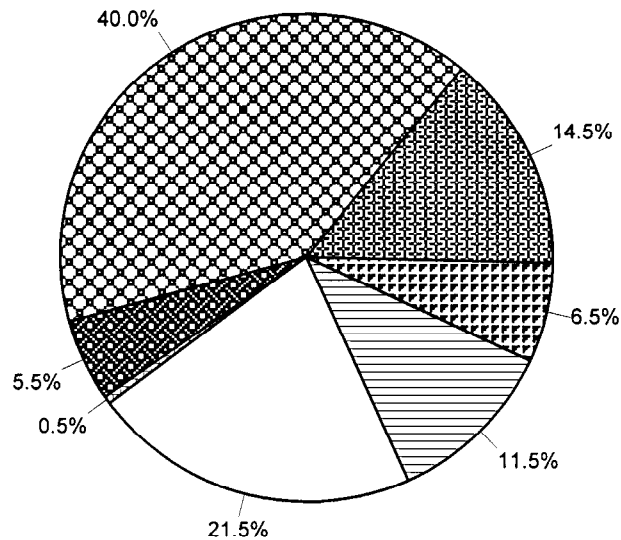
*Examples of errors and accidents represent at least 50% of reports in each category.

ERROR AND ACCIDENT REPORTS

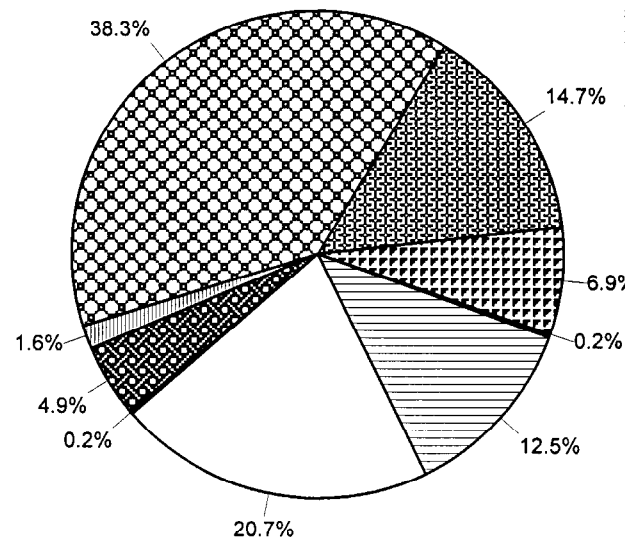
ALL BLOOD AND PLASMA ESTABLISHMENTS

NON-REPORTABLE ERRORS/ACCIDENTS

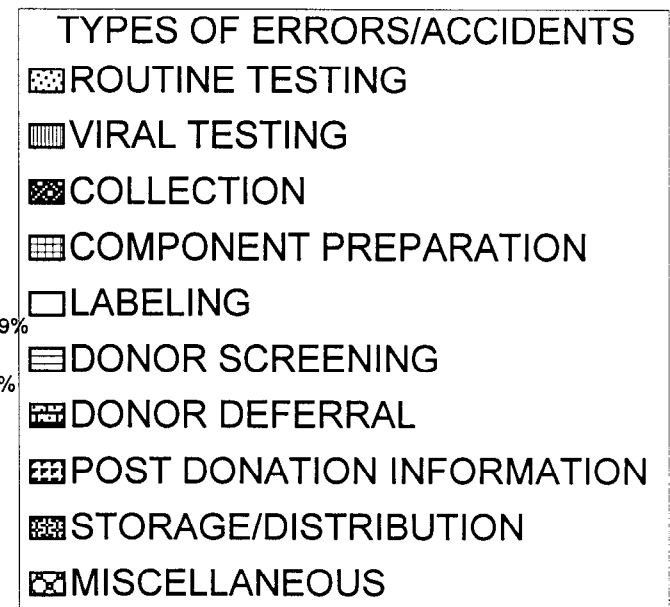
FY98



SECOND QUARTER



YEAR-TO-DATE



REPORTS RECEIVED SECOND QUARTER (1/1/97 - 3/31/98) = 200

REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 3/31/98) = 449

FY98 YEAR-TO-DATE

NON-REPORTABLE ERRORS/ACCIDENTS - 449 (7.1% of total reports)

Top Three Categories of Errors/Accidents:

Miscellaneous 172 (38.3% of non-reportables)

**Examples:*

- No products made available for distribution
- Recordkeeping error/accident - record is incorrect or not reviewed, testing and labeling acceptable
- Destruction records incomplete, final disposition of product unknown
(documentation indicates unit was suitable at time of distribution)
- Recall procedures not followed (e.g., recall not performed within appropriate time)

Labeling - 93 (20.7% of non-reportables)

**Examples:*

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

Storage and Distribution 66 (14.7% 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
SECOND QUARTER - FY98**

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

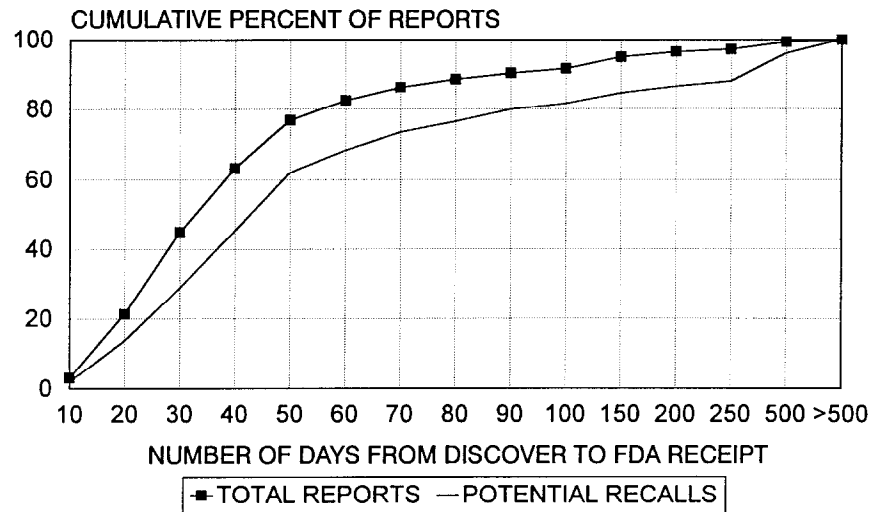
CUMULATIVE PERCENT OF REPORTS	ARC (DAYS)	NON-ARC LICENSED (DAYS)	UNLICENSED (DAYS)	PLASMA (DAYS)	TOTAL (DAYS)
10%	16	15	8	11	15
25%	21	21	14	18	21
50%	30	35	21	43	33
75%	40	63	32	80	49
90%	48	120	49	191	86
# REPORTS	1249	1403	37	311	3000
RANGE	5-706	4-1065	7-101	3-411	3-1065

**ERROR AND ACCIDENT REPORTS
RECEIVED 10/1/97 - 3/31/98**

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

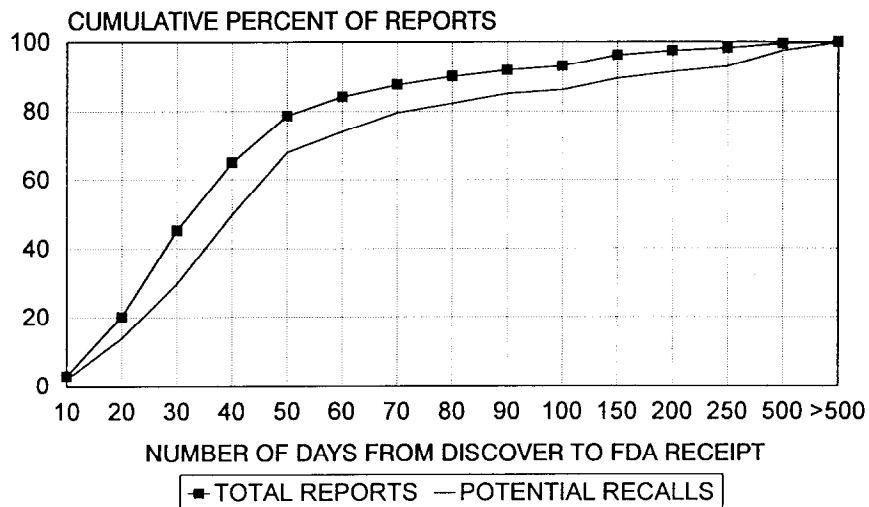
CUMULATIVE PERCENT OF REPORTS	ARC (DAYS)	NON-ARC LICENSED (DAYS)	UNLICENSED (DAYS)	PLASMA (DAYS)	TOTAL (DAYS)
10%	16	15	8	10	15
25%	22	22	14	18	22
50%	30	35	21	39	32
75%	39	61	37	80	48
90%	48	109	82	161	80
TOTAL REPORTS	2646	2642	65	544	5897
RANGE	5-706	4-1065	5-727	3-445	3-1065

ERROR AND ACCIDENT REPORTS REPORTING TIME ALL REPORTING BLOOD ESTABLISHMENTS SECOND QUARTER FY98



TOTAL REPORTS = 3000
POTENTIAL RECALLS = 402

ERROR AND ACCIDENT REPORTS REPORTING TIME ALL REPORTING BLOOD ESTABLISHMENTS YEAR -TO-DATE FY98

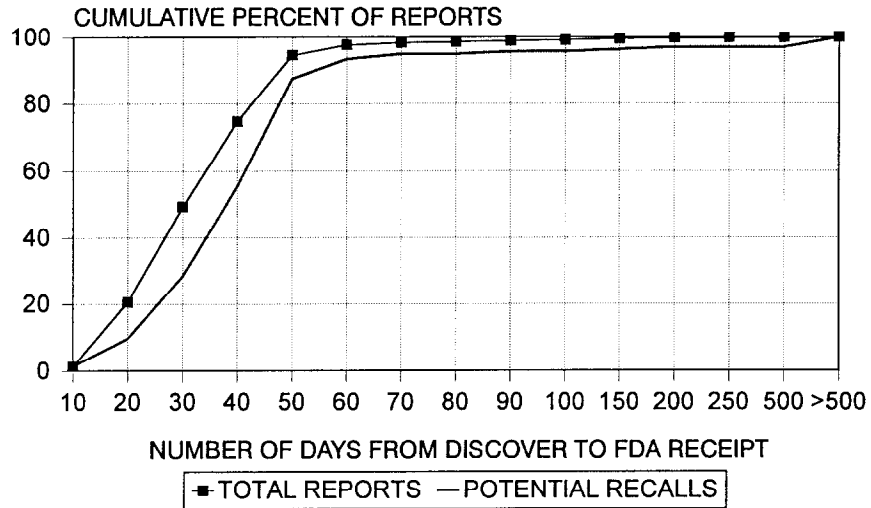


TOTAL REPORTS = 5897
POTENTIAL RECALLS = 785

ERROR AND ACCIDENT REPORTS

REPORTING TIME
AMERICAN RED CROSS

SECOND QUARTER FY98

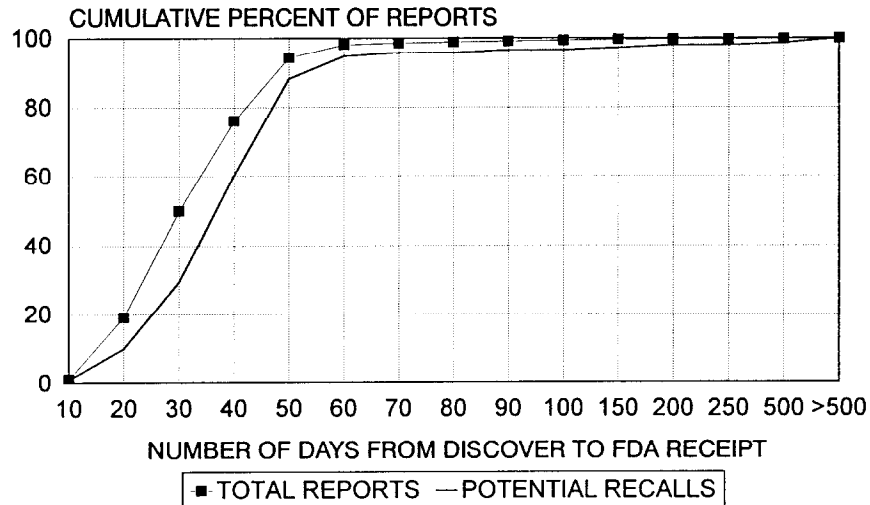


TOTAL REPORTS = 1249
POTENTIAL RECALLS = 134

ERROR AND ACCIDENT REPORTS

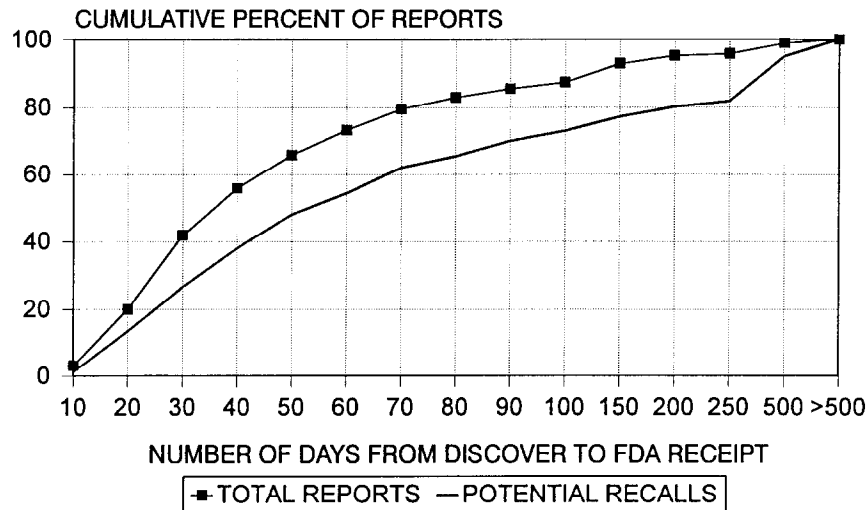
REPORTING TIME
AMERICAN RED CROSS

YEAR-TO-DATE FY98



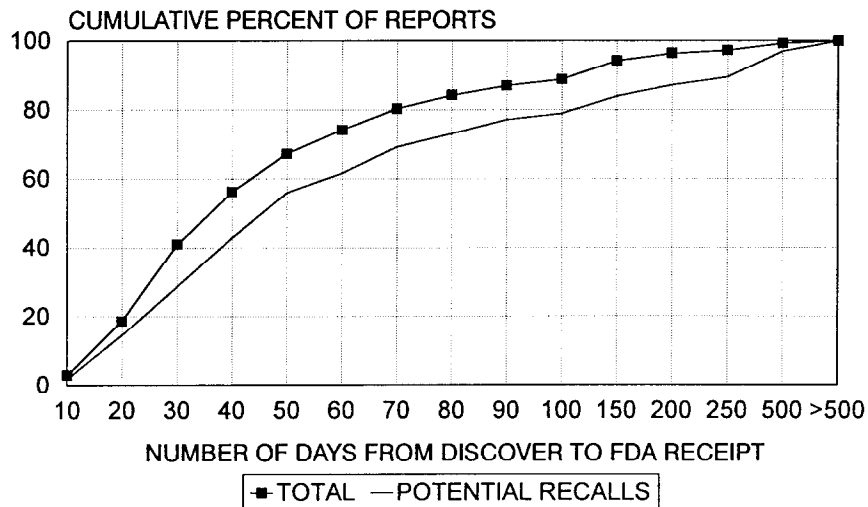
TOTAL REPORTS = 2646
POTENTIAL RECALLS = 289

ERROR AND ACCIDENT REPORTS REPORTING TIME NON-ARC LICENSED BLOOD BANKS SECOND QUARTER FY98



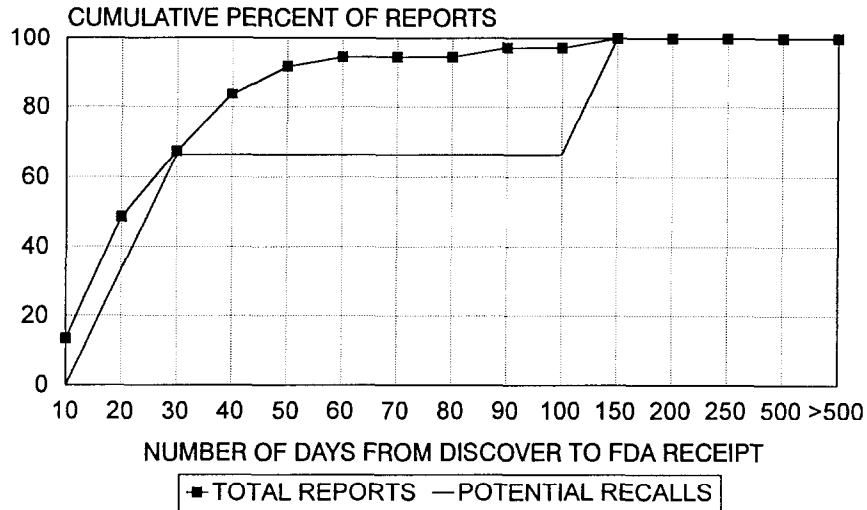
TOTAL REPORTS = 1403
POTENTIAL RECALLS = 231

ERROR AND ACCIDENT REPORTS REPORTING TIME NON-ARC LICENSED BLOOD BANKS YEAR-TO-DATE FY98



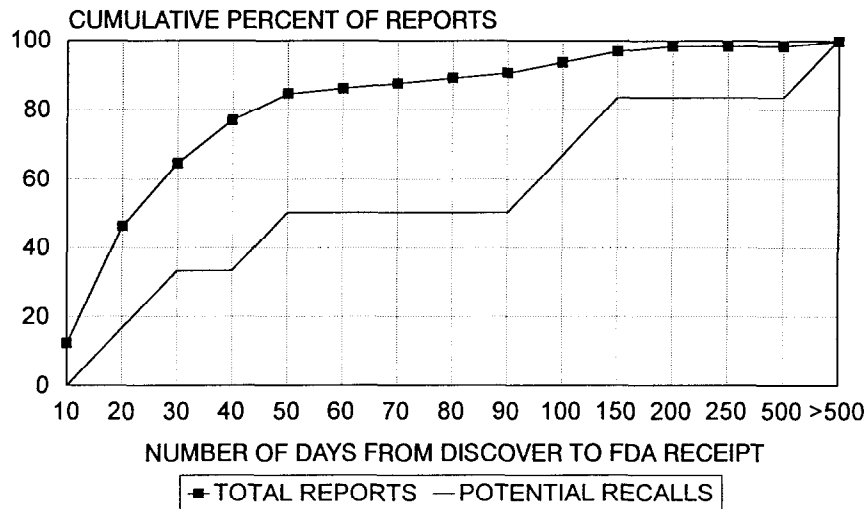
TOTAL REPORTS = 2642
POTENTIAL RECALLS = 440

ERROR AND ACCIDENT REPORTS REPORTING TIME UNLICENSED BLOOD BANKS SECOND QUARTER FY98



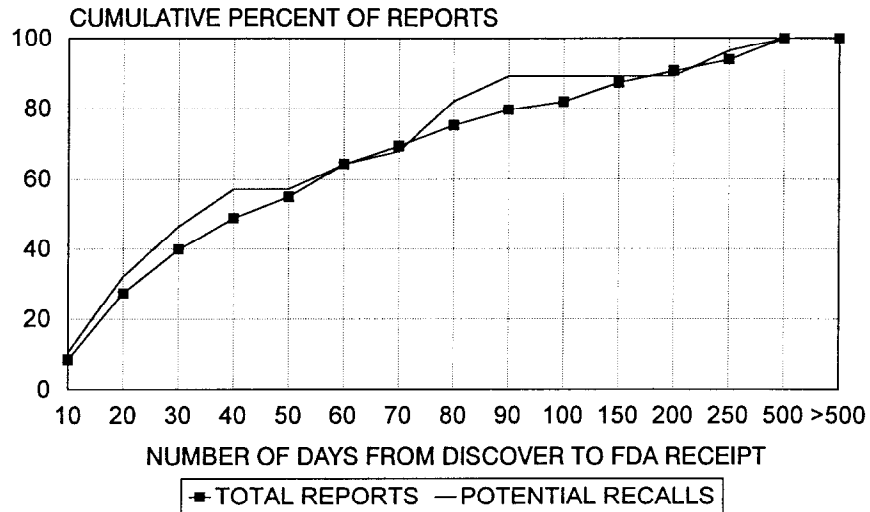
TOTAL REPORTS = 37
POTENTIAL RECALLS = 3

ERROR AND ACCIDENT REPORTS REPORTING TIME UNLICENSED BLOOD BANKS YEAR-TO-DATE FY98



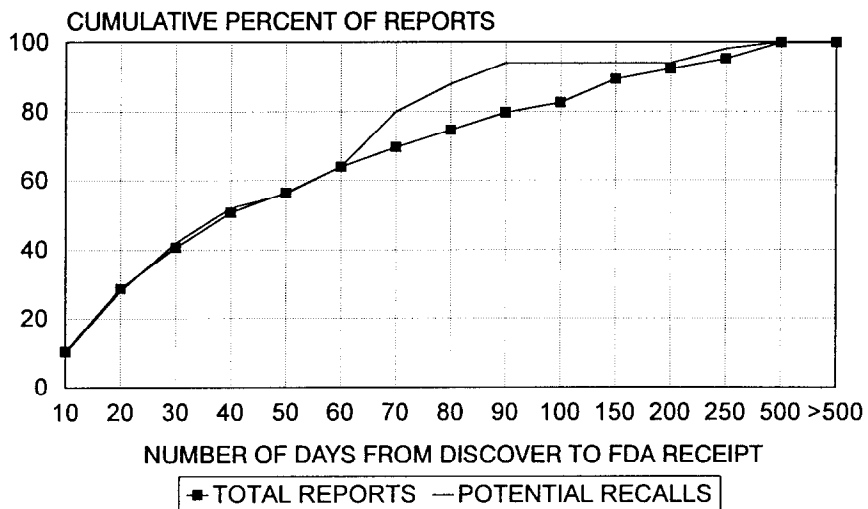
TOTAL REPORTS = 65
POTENTIAL RECALLS = 6

ERROR AND ACCIDENT REPORTS REPORTING TIME PLASMA CENTERS SECOND QUARTER FY98



TOTAL REPORTS = 311
POTENTIAL RECALLS = 28

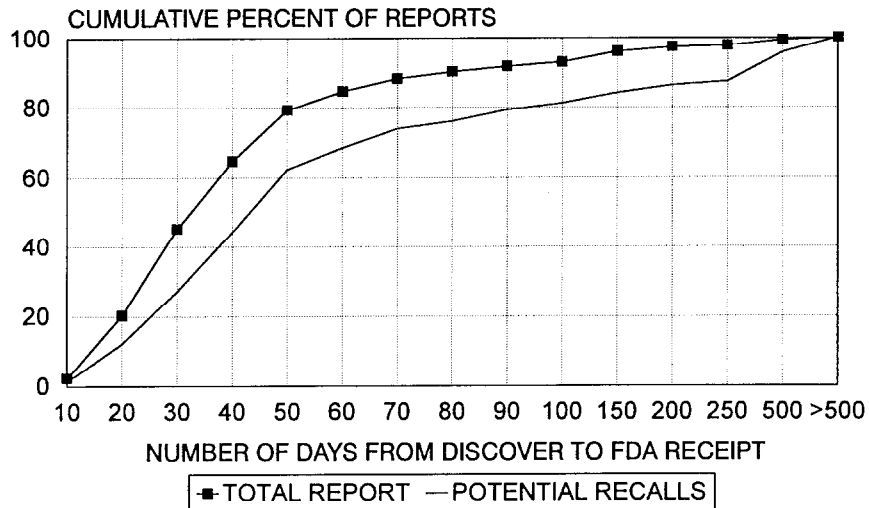
ERROR AND ACCIDENT REPORTS REPORTING TIME PLASMA CENTERS YEAR-TO-DATE FY98



TOTAL REPORTS = 544
POTENTIAL RECALLS = 50

ERROR AND ACCIDENT REPORTS

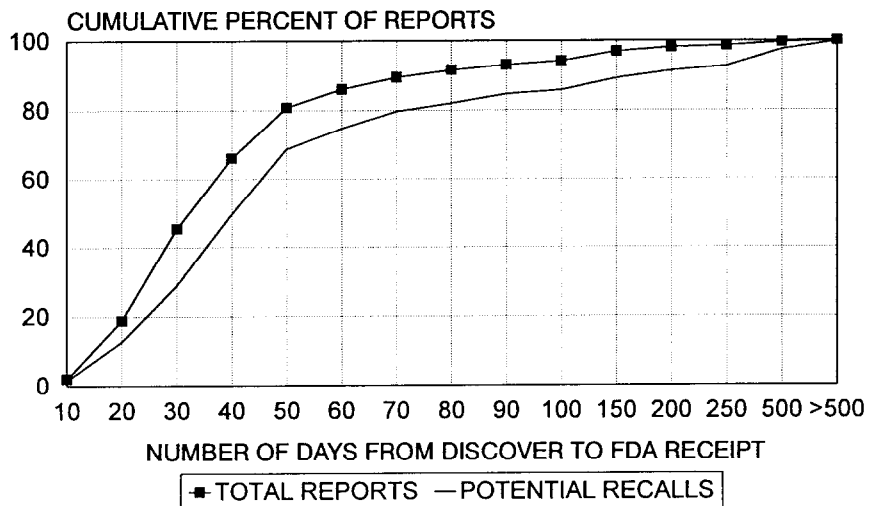
REPORTING TIME
ALL LICENSED BLOOD BANKS
SECOND QUARTER FY98



TOTAL REPORTS = 2652
POTENTIAL RECALLS = 371

ERROR AND ACCIDENT REPORTS

REPORTING TIME
ALL LICENSED BLOOD BANKS
YEAR-TO-DATE FY98



TOTAL REPORTS = 5288
POTENTIAL RECALLS = 729