

## MEMORANDUM

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

DATE: MAY - 5 1998

FROM: Sharon O'Callaghan, <sup>doc</sup>CSO,  
Division of Inspections and Surveillance (HFM-650)

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

TO: Director, Division of Inspections and Surveillance (HFM-650) *Boyd Doyle* 5/7/98

Between October 1, 1997 and December 31, 1997, the Division of Inspections and Surveillance received 1,519 error and accident reports from the American Red Cross (ARC), 1,355 error and accident reports from non-ARC licensed blood establishments, 28 error and accident reports from unlicensed registered blood establishments, 239 error and accident reports from plasma centers, 6 reports from transfusion services, 3 reports from blood derivative manufacturers, 3 reports from in-vitro diagnostic manufacturers, and 1 report from a vaccine manufacturer. A total of 3,154 error and accident reports were received. There were 384 (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, 250 (7.9%) 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  
Non-Blood Manufacturers
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Total, Potential Recalls
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Year-To-Date
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All Reporting Blood Establishments, All Licensed Blood Establishments

**FIRST QUARTER FY98  
ALL REPORTING ESTABLISHMENTS**

	TOTAL REPORTS	POTENTIAL RECALLS
AMERICAN RED CROSS	1519	155
NON-ARC LICENSED BLOOD BANKS	1355	202
UNLICENSED BLOOD BANKS	28	3
TRANSFUSION SERVICES	6	0
PLASMA CENTERS	239	22
BLOOD DERIVATIVE MANUFACTURER	3	0
IN-VITRO DIAGNOSTIC MANUFACTURER	3	2
VACCINE MANUFACTURER	1	0
ALLERGENICS MANUFACTURER	0	0
THERAPEUTIC MANUFACTURER	0	0
<i>TOTAL</i>	3154	384

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

**FIRST 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	31	67	5	2	0	105	3.3%
VIRAL TESTING	6	24	2	0	1	33	1.0%
COLLECTION	24	12	0	0	1	37	1.2%
COMPONENT PREPARATION	38	34	1	0	0	73	2.3%
LABELING	156	154	3	0	2	315	10.0%
DONOR SCREENING	98	144	1	0	16	259	8.2%
DONOR DEFERRAL	7	15	0	0	1	23	0.7%
POST DONATION INFO	961	734	7	0	196	1898	60.3%
STORAGE/DISTRIBUTION	154	126	6	3	13	302	9.6%
MISCELLANEOUS	44	45	3	1	9	102	3.2%
<b>TOTAL</b>	<b>1519</b>	<b>1355</b>	<b>28</b>	<b>6</b>	<b>239</b>	<b>3147</b>	<b>100%</b>

**POTENTIAL RECALLS**

TYPE OF ERROR/ACCIDENT	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
ROUTINE TESTING	0	3	0	0	0	3	0.8%
VIRAL TESTING	4	8	1	0	1	14	3.7%
COLLECTION	10	7	0	0	1	18	4.7%
COMPONENT PREPARATION	23	28	0	0	0	51	13.4%
LABELING	21	21	2	0	0	44	11.5%
DONOR SCREENING	49	89	0	0	8	146	38.2%
DONOR DEFERRAL	7	13	0	0	1	21	5.5%
POST DONATION INFO	3	3	0	0	3	9	2.4%
STORAGE/DISTRIBUTION	38	30	0	0	8	76	19.9%
MISCELLANEOUS	0	0	0	0	0	0	0.0%
<b>TOTAL</b>	<b>155</b>	<b>202</b>	<b>3</b>	<b>0</b>	<b>22</b>	<b>382</b>	<b>100%</b>

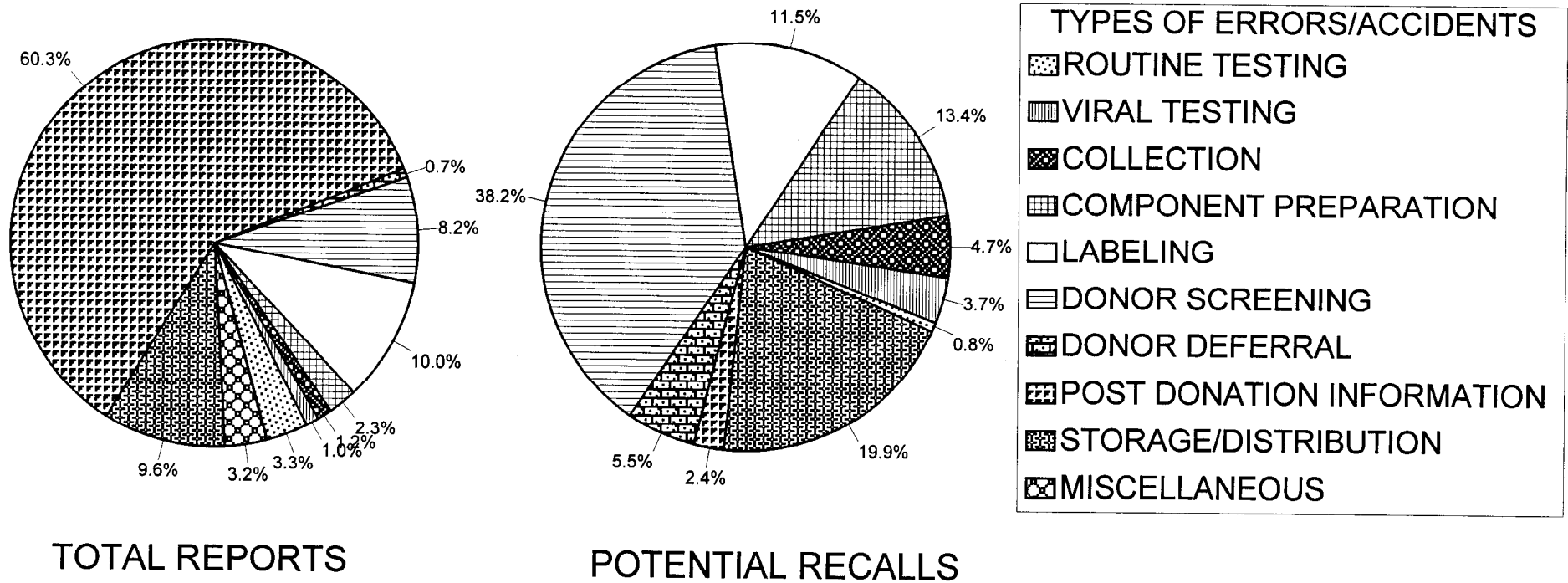
FIRST QUARTER - FY98  
NON-BLOOD MANUFACTURERS

TYPE OF ERROR/ACCIDENT	IN-VITRO DIAGNOSTIC		DERIVATIVE		VACCINE		TOTAL		RECALL	
	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL				
LABELING	1	1	0	0	0	0	1	14.3%	1	50.0%
DECREASE IN POTENCY	1	1	0	0	0	0	1	14.3%	1	50.0%
SHIPPED/STORED AT INCORRECT TEMPERATURE	0	0	1	0	0	0	1	14.3%	0	0.0%
SOURCE MATERIAL WITHDRAWN DUE TO CJD RISK	0	0	1	0	0	0	1	14.3%	0	0.0%
STERILITY COMPROMISED - AIR CONTAMINATION	0	0	1	0	0	0	1	14.3%	0	0.0%
UNAPPROVED SEED PASSAGE USED	0	0	0	0	1	0	1	14.3%	0	0.0%
NON-REPORTABLE - PRODUCTS NOT MADE AVAILABLE	1	0	0	0	0	0	1	14.3%	0	0.0%
<b>TOTAL</b>	<b>3</b>	<b>2</b>	<b>3</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>7</b>	<b>100.0%</b>	<b>2</b>	<b>100.0%</b>

# ERROR AND ACCIDENT REPORTS

## ALL BLOOD AND PLASMA ESTABLISHMENTS

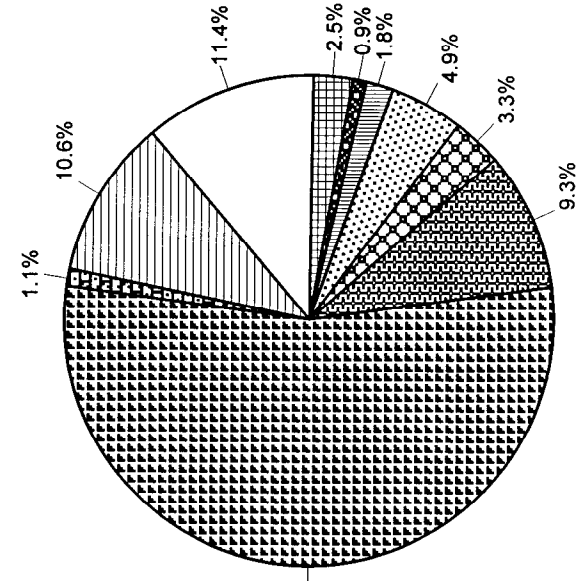
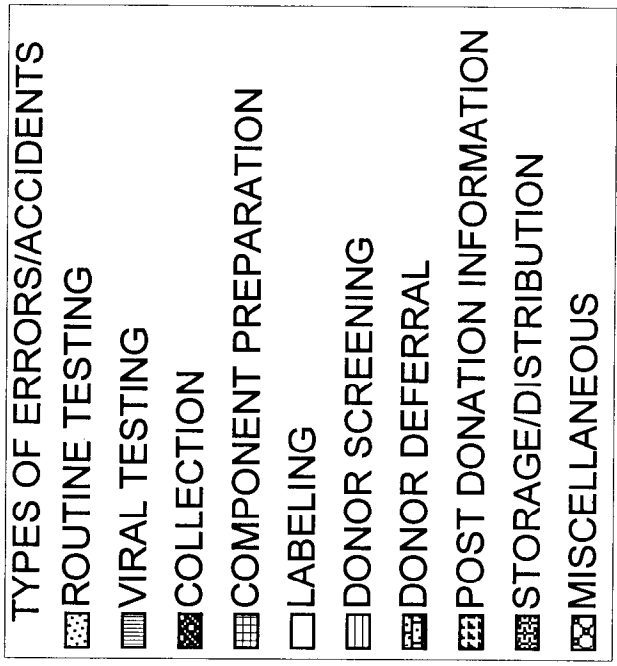
### FIRST QUARTER - FY98



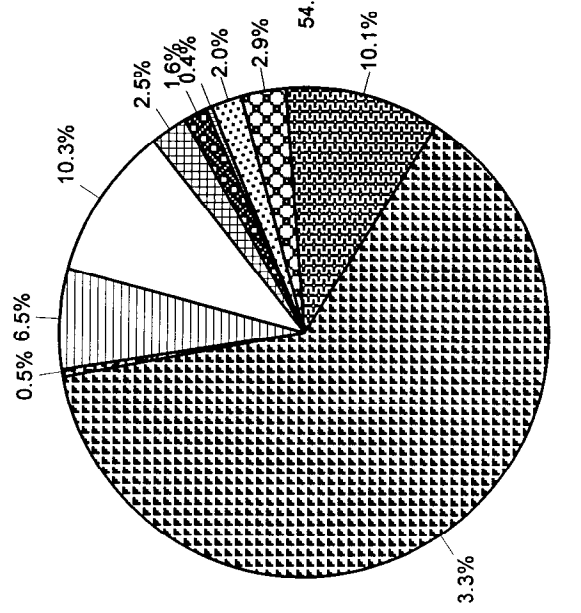
TOTAL REPORTS RECEIVED (10/1/97 - 12/31/97) = 3147  
 POTENTIAL RECALLS = 382

# ERROR AND ACCIDENT REPORTS FIRST QUARTER

FY98



AMERICAN RED CROSS

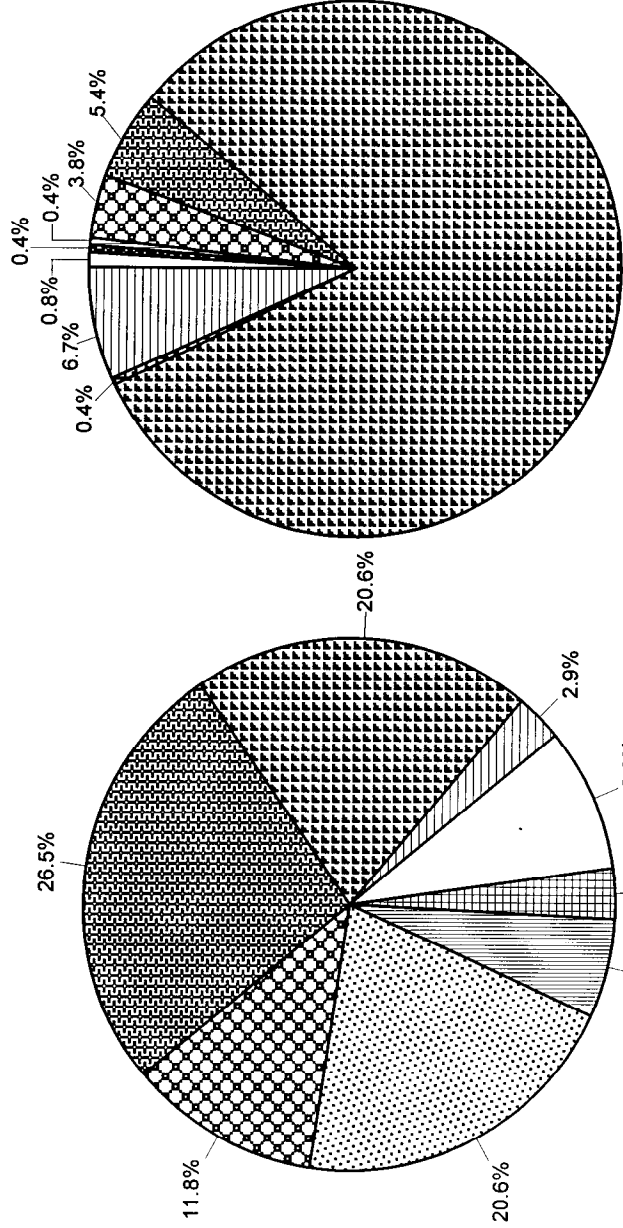


NON-ARC LICENSED  
BLOOD BANKS

REPORTS RECEIVED (10/1/97 - 12/31/97)  
 AMERICAN RED CROSS = 1519  
 NON-ARC LICENSED BLOOD BANKS = 1355

# ERROR AND ACCIDENT REPORTS FIRST QUARTER

FY98



UNLICENSED  
BLOOD BANKS

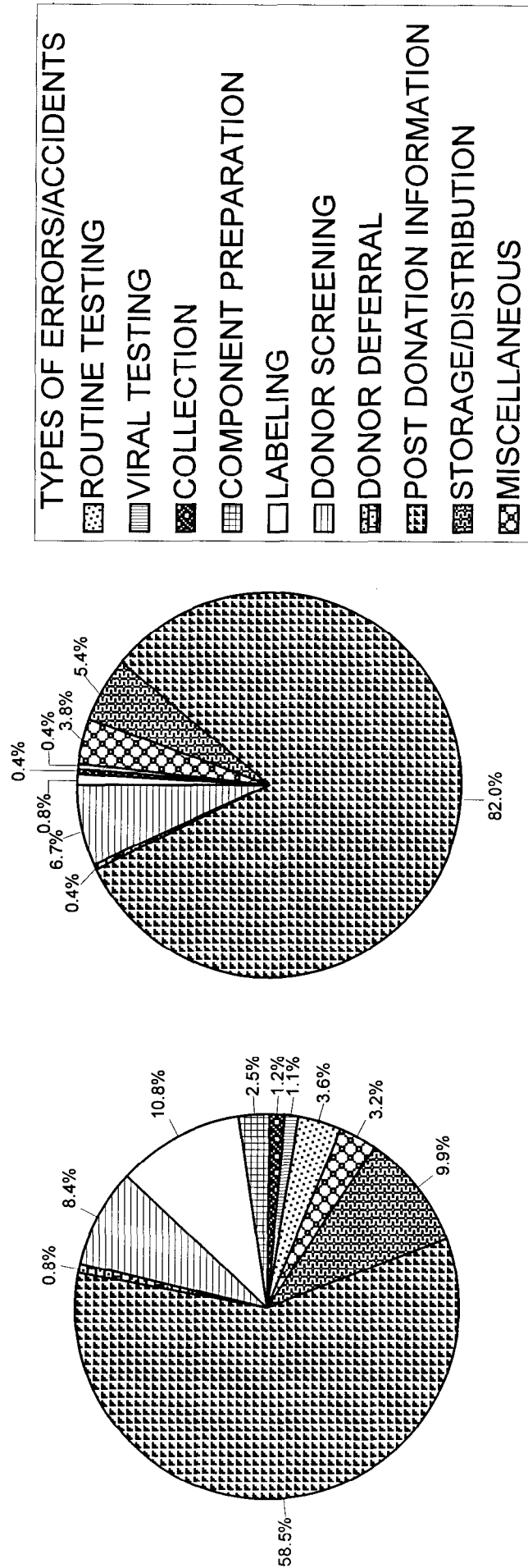
PLASMA CENTERS

REPORTS RECEIVED (10/1/97 - 12/31/97)  
UNLICENSED BLOOD BANKS = 34 (6 REPORTS - TRANSFUSION SERVICE)  
PLASMA CENTERS = 239



# ERROR AND ACCIDENT REPORTS FIRST QUARTER

FY98



BLOOD BANKS

PLASMA CENTERS

REPORTS RECEIVED 10/1/97 - 12/31/97

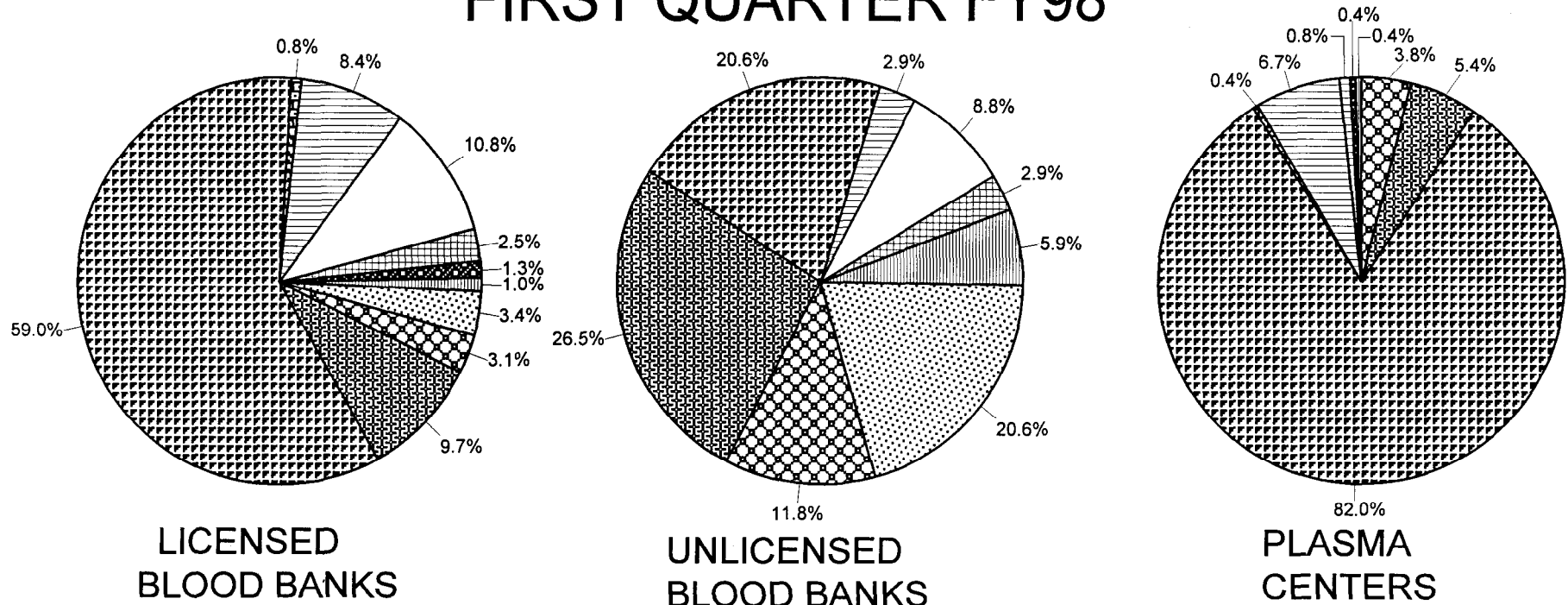
BLOOD BANKS = 2908

PLASMA CENTERS = 239

# ERROR AND ACCIDENT REPORTS

## BLOOD BANKS VERSUS PLASMA CENTERS

### FIRST QUARTER FY98



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

REPORTS RECEIVED 10/1/97 - 12/31/97  
 LICENSED BLOOD BANKS = 2874  
 UNLICENSED BLOOD BANKS = 34  
 PLASMA CENTERS = 239

FIRST QUARTER - FY98  
**BLOOD AND PLASMA ESTABLISHMENTS**

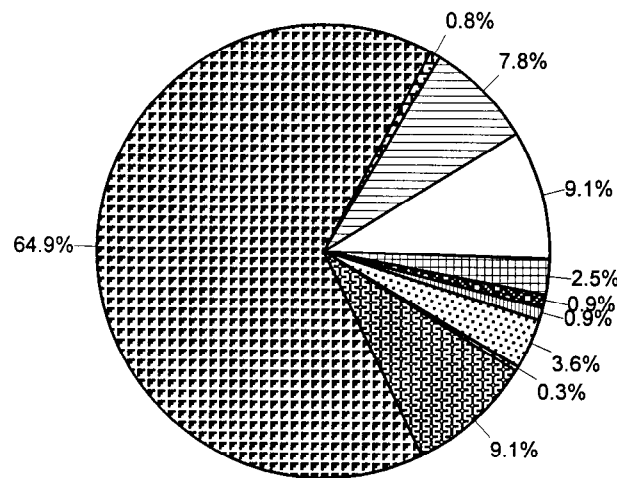
TYPE OF ERROR/ACCIDENT	NON-REPORTABLE	REPORTABLE	TOTAL	%NON-REPORTABLE
ROUTINE TESTING	0	105	105	0.0%
VIRAL TESTING	7	26	33	21.2%
COLLECTION	10	27	37	27.0%
COMPONENT PREPARATION	1	72	73	1.4%
LABELING	50	265	315	15.9%
DONOR SCREENING	33	226	259	12.7%
DONOR DEFERRAL	1	22	23	4.3%
POST DONATION INFORMATION	18	1880	1898	0.9%
STORAGE/DISTRIBUTION	37	265	302	12.3%
MISCELLANEOUS	92	10	102	90.2%
<b>TOTAL</b>	<b>249</b>	<b>2898</b>	<b>3147</b>	<b>7.9%</b>

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

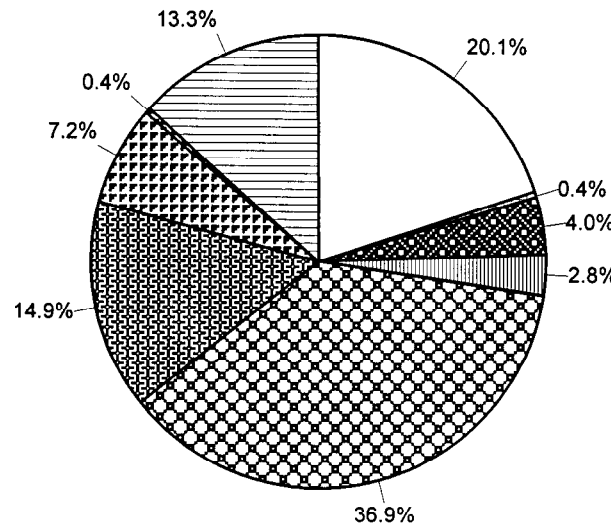
# ERROR AND ACCIDENT REPORTS

## ALL BLOOD AND PLASMA ESTABLISHMENTS

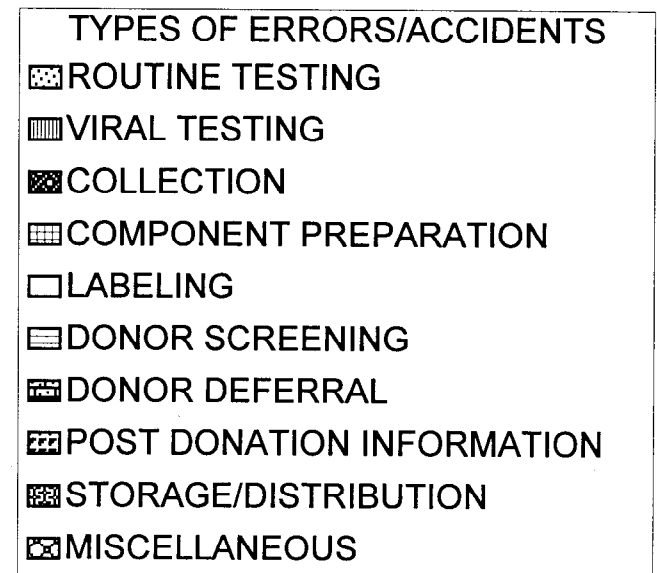
### FIRST QUARTER - FY98



REPORTABLE E/A's



NON-REPORTABLE E/A'S



REPORTS RECEIVED (10/1/97 - 12/31/97)  
 REPORTABLE ERRORS/ACCIDENTS = 2898  
 NON-REPORTABLE ERRORS/ACCIDENTS = 249

## FY98 YEAR-TO-DATE

REPORTABLE ERRORS/ACCIDENTS - 2898 (92.1% of total reports)

### Top Three Categories of Errors/Accidents:

Post Donation Information - 1880 (64.9% 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
- Donor had a history of IV drug use

Storage/Distribution - 265 (9.1% 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

Labeling - 265 (9.1% 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 ABO/Rh label

## FY98 YEAR-TO-DATE

NON-REPORTABLE ERRORS/ACCIDENTS - 249 (7.9% of total reports)

### Top Three Categories of Errors/Accidents:

Miscellaneous 92 ( 36.9% of non-reportables)

*\*Examples:*

- No products made available for distribution
- Records destroyed or lost
- Destruction records incomplete, final disposition of product unknown  
(documentation indicates unit was suitable at time of distribution)
- Recordkeeping error/accident - record is incorrect or not reviewed, testing and labeling are acceptable

Labeling - 50 (20.1% 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
- Directed unit, suitable for homologous use, labeled with incorrect recipient information, (e.g., name, social security number or date of birth)

Storage/Distribution - 37 (14.9% of non-reportables)

*\*Example:*

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

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

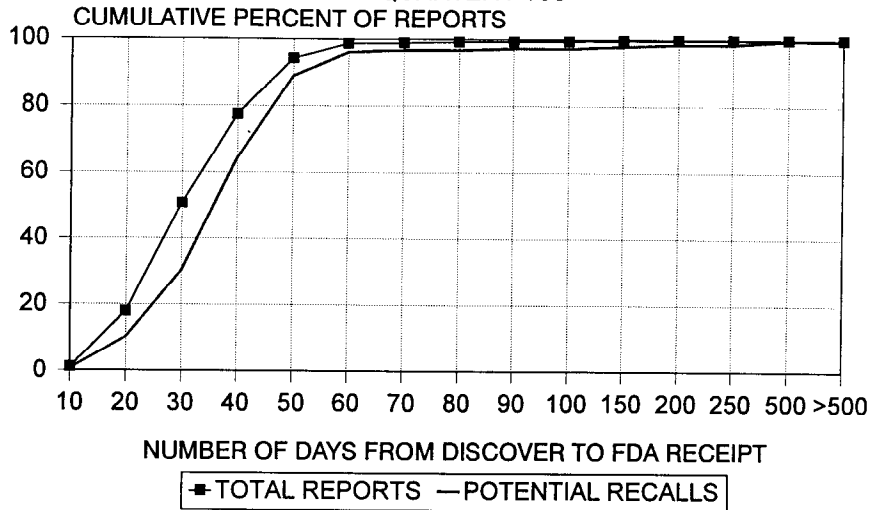
The following table and graphs show the time periods in which the reports were received by CBER. The evaluation of timeliness is limited to only reports that met the threshold for reporting.

**ERROR AND ACCIDENT REPORTS  
FIRST QUARTER - FY98**

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

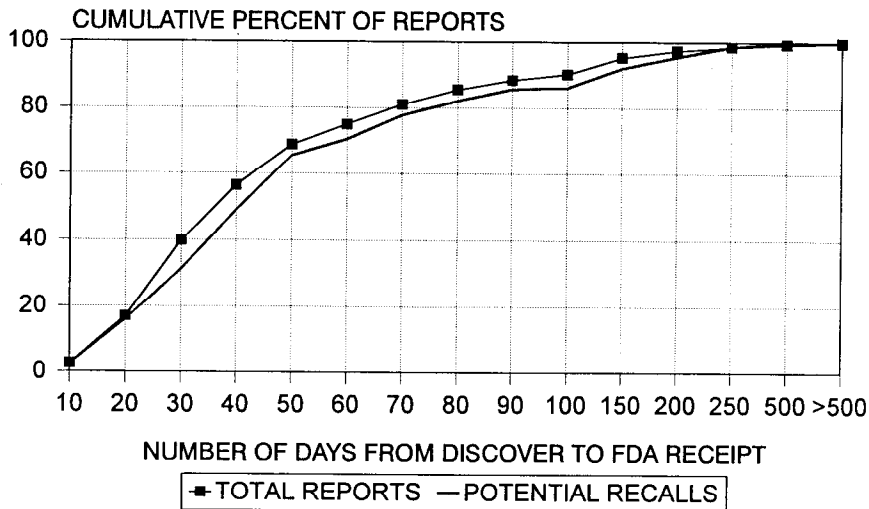
<b>CUMULATIVE PERCENT OF REPORTS</b>	<b>ARC (DAYS)</b>	<b>NON-ARC LICENSED (DAYS)</b>	<b>UNLICENSED (DAYS)</b>	<b>PLASMA (DAYS)</b>	<b>TOTAL (DAYS)</b>
10%	16	16	9	9	15
25%	22	24	14	17	22
50%	30	36	22	35	32
75%	39	60	47	82	46
90%	47	97	148	129	75
<b># REPORTS</b>	1397	1240	28	233	2898
<b>RANGE</b>	7-341	5-975	5-727	3-445	3-975

## ERROR AND ACCIDENT REPORTS REPORTING TIME AMERICAN RED CROSS FIRST QUARTER FY98



TOTAL REPORTS = 1397  
POTENTIAL RECALLS = 155

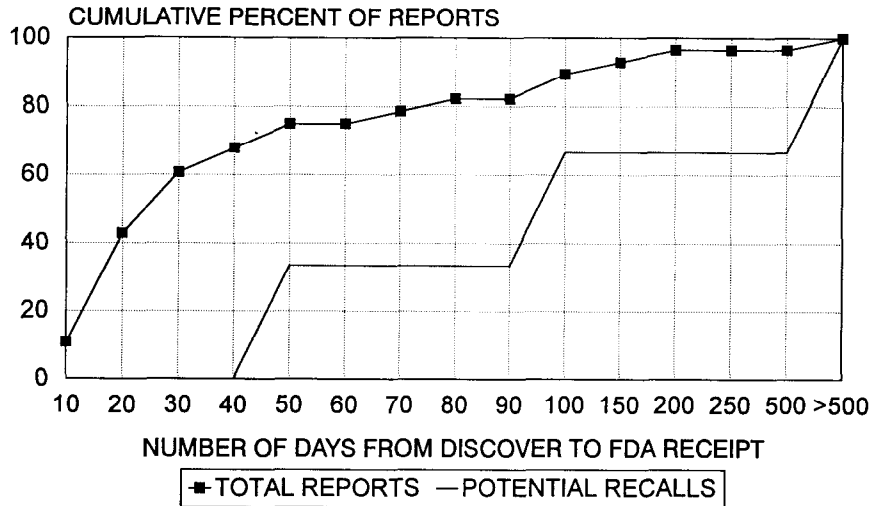
## ERROR AND ACCIDENT REPORTS REPORTING TIME NON-ARC LICENSED BLOOD BANKS FIRST QUARTER FY98



TOTAL REPORTS = 1240  
POTENTIAL RECALLS = 202

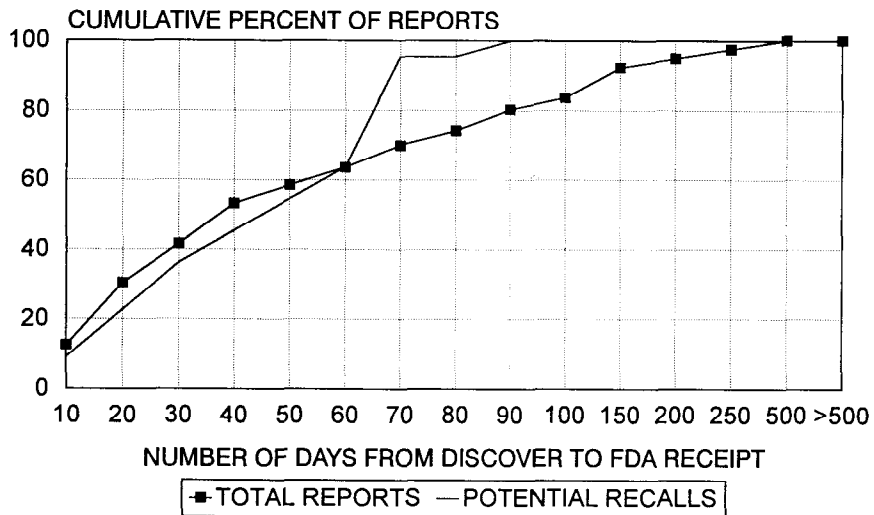


## ERROR AND ACCIDENT REPORTS REPORTING TIME UNLICENSED BLOOD BANKS FIRST QUARTER FY98



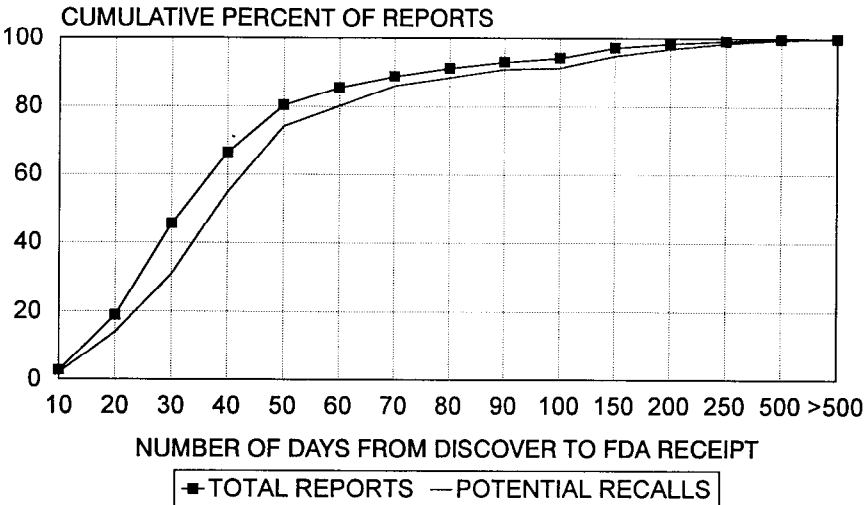
TOTAL REPORTS = 28  
POTENTIAL RECALLS = 3

## ERROR AND ACCIDENT REPORTS REPORTING TIME PLASMA CENTERS FIRST QUARTER FY98



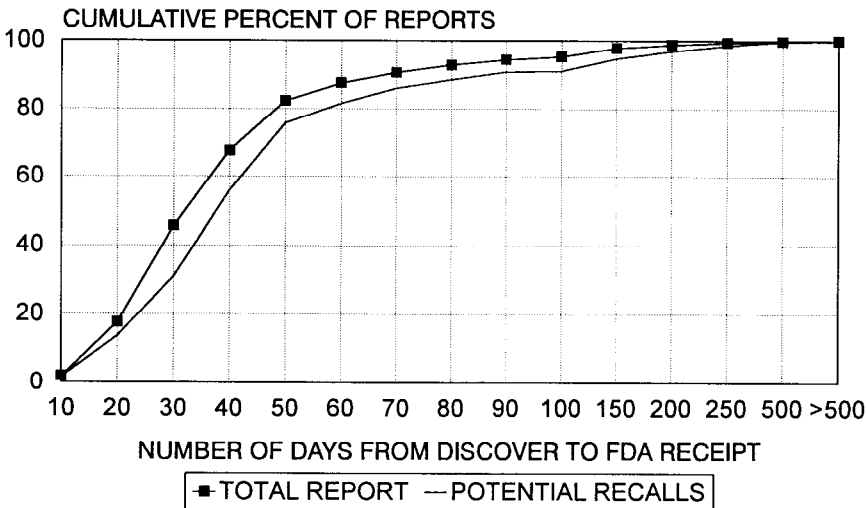
TOTAL REPORTS = 233  
POTENTIAL RECALLS = 22

# ERROR AND ACCIDENT REPORTS REPORTING TIME ALL REPORTING BLOOD ESTABLISHMENTS FIRST QUARTER FY98



TOTAL REPORTS = 2898  
POTENTIAL RECALLS = 382

# ERROR AND ACCIDENT REPORTS REPORTING TIME ALL LICENSED BLOOD BANKS FIRST QUARTER FY98



TOTAL REPORTS = 2637  
POTENTIAL RECALLS = 357