

## MEMORANDUM

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

DATE: FEB 11 1999

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

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

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

Between July 1, 1998 and September 30, 1998, the Division of Inspections and Surveillance received 1,720 error and accident reports from the American Red Cross (ARC), 1,480 error and accident reports from non-ARC licensed blood establishments, 57 error and accident reports from unlicensed registered blood establishments, 269 error and accident reports from plasma centers, 7 reports from transfusion services, 6 reports from blood derivative manufacturers, 9 reports from in-vitro diagnostic manufacturers, and 1 report from an allergenic manufacturer. A total of 3,549 error and accident reports were received. There were 460 (13.0%) 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, 236 (6.7%) 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 September 30, 1998, the Division of Inspections and Surveillance received a total of 13,232 error and accident reports. There were 1692 (12.8%) 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, 903 (6.8%) 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

- 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 Reports
- 5 - Pie charts - All Blood and Plasma Establishments  
Potential Recalls
- 6 - Pie charts - Types of Errors/Accidents  
ARC
- 7 - Pie charts - Types of Errors/Accidents  
Non-ARC Licensed Blood Banks
- 8 - Pie charts - Types of Errors/Accidents  
Unlicensed Blood Banks
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Plasma Centers
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Blood Banks, Plasma Centers
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Licensed Blood Banks, Unlicensed Blood Banks, Plasma Centers
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Blood and Plasma Establishments  
Non-Reportable, Reportable, Total
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Reportable E/A's
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Year-To-Date
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Year-To-Date
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ARC
- 20 - Line graphs - Reporting Time  
Non-ARC Licensed Blood Banks
- 21 - Line graphs - Reporting Time  
Unlicensed Blood Banks
- 22 - Line graphs - Reporting Time  
Plasma Centers
- 23 - Line graphs - Reporting Time  
All Licensed Blood Banks

FOURTH QUARTER - FY98  
**ALL REPORTING ESTABLISHMENTS**

|  | TOTAL REPORTS RECEIVED |              | POTENTIAL RECALLS |              |
|--|------------------------|--------------|-------------------|--------------|
|  | FOURTH QUARTER         | YEAR-TO-DATE | FOURTH QUARTER    | YEAR-TO-DATE |
| AMERICAN RED CROSS                     | 1720                   | 6035         | 124               | 528          |
| NON-ARC LICENSED BLOOD BANKS           | 1480                   | 5819         | 299               | 1045         |
| UNLICENSED BLOOD BANKS                 | 57                     | 211          | 6                 | 18           |
| TRANSFUSION SERVICES                   | 7                      | 19           | 0                 | 0            |
| PLASMA CENTERS                         | 269                    | 1103         | 23                | 86           |
| BLOOD DERIVATIVE MANUFACTURER          | 6                      | 17           | 0                 | 0            |
| IN-VITRO DIAGNOSTIC MANUFACTURER       | 9                      | 19           | 7                 | 12           |
| VACCINE MANUFACTURER                   | 0                      | 3            | 0                 | 0            |
| ALLERGENICS MANUFACTURER               | 1                      | 3            | 1                 | 3            |
| THERAPEUTICS MANUFACTURER              | 0                      | 3            | 0                 | 0            |
| TOTAL                                  | 3549                   |              | 460               |              |
| TOTAL - YEAR-TO-DATE 10/1/97 - 9/30/98 |                        | 13232        |                   | 1692         |

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

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

**TOTAL ERRORS AND ACCIDENTS**

| TYPE OF ERROR/ACCIDENT | ARC         | NON-ARC LICENSED<br>BLOOD BANKS | UNLICENSED<br>BLOOD BANKS | TRANSFUSION<br>SERVICES | PLASMA<br>CENTERS | TOTAL       |             |
|------------------------|-------------|---------------------------------|---------------------------|-------------------------|-------------------|-------------|-------------|
| ROUTINE TESTING        | 31          | 52                              | 2                         | 0                       | 0                 | 85          | 2.4%        |
| VIRAL TESTING          | 17          | 135                             | 3                         | 0                       | 1                 | 156         | 4.4%        |
| COLLECTION             | 33          | 11                              | 1                         | 0                       | 0                 | 45          | 1.3%        |
| COMPONENT PREPARATION  | 20          | 24                              | 1                         | 1                       | 0                 | 46          | 1.3%        |
| LABELING               | 148         | 160                             | 10                        | 0                       | 0                 | 318         | 9.0%        |
| DONOR SCREENING        | 63          | 130                             | 2                         | 0                       | 21                | 216         | 6.1%        |
| DONOR DEFERRAL         | 4           | 8                               | 2                         | 0                       | 6                 | 20          | 0.6%        |
| POST DONATION INFO     | 1228        | 753                             | 10                        | 0                       | 203               | 2194        | 62.1%       |
| STORAGE/DISTRIBUTION   | 136         | 168                             | 14                        | 6                       | 14                | 338         | 9.6%        |
| MISCELLANEOUS          | 40          | 39                              | 12                        | 0                       | 24                | 115         | 3.3%        |
| <b>TOTAL</b>           | <b>1720</b> | <b>1480</b>                     | <b>57</b>                 | <b>7</b>                | <b>269</b>        | <b>3533</b> | <b>100%</b> |

**POTENTIAL RECALLS**

| TYPE OF ERROR/ACCIDENT | ARC        | NON-ARC LICENSED<br>BLOOD BANKS | UNLICENSED<br>BLOOD BANKS | TRANSFUSION<br>SERVICES | PLASMA<br>CENTERS | TOTAL      |             |
|------------------------|------------|---------------------------------|---------------------------|-------------------------|-------------------|------------|-------------|
| ROUTINE TESTING        | 0          | 0                               | 0                         | 0                       | 0                 | 0          | 0.0%        |
| VIRAL TESTING          | 4          | 127                             | 1                         | 0                       | 0                 | 132        | 29.2%       |
| COLLECTION             | 9          | 6                               | 0                         | 0                       | 0                 | 15         | 3.3%        |
| COMPONENT PREPARATION  | 14         | 11                              | 0                         | 0                       | 0                 | 25         | 5.5%        |
| LABELING               | 19         | 28                              | 1                         | 0                       | 0                 | 48         | 10.6%       |
| DONOR SCREENING        | 36         | 67                              | 1                         | 0                       | 11                | 115        | 25.4%       |
| DONOR DEFERRAL         | 3          | 7                               | 2                         | 0                       | 6                 | 18         | 4.0%        |
| POST DONATION INFO     | 11         | 4                               | 0                         | 0                       | 1                 | 16         | 3.5%        |
| STORAGE/DISTRIBUTION   | 28         | 48                              | 1                         | 0                       | 5                 | 82         | 18.1%       |
| MISCELLANEOUS          | 0          | 1                               | 0                         | 0                       | 0                 | 1          | 0.2%        |
| <b>TOTAL</b>           | <b>124</b> | <b>299</b>                      | <b>6</b>                  | <b>0</b>                | <b>23</b>         | <b>452</b> | <b>100%</b> |

FOURTH QUARTER - FY98  
NON-BLOOD MAUFACTURERS

| TYPE OF ERROR/ACCIDENT | DERIVATITVE |          | IN-VITRO DIAGNOSTIC |          | VACCINE  |          | ALLERGENIC |          | THERAPUETIC |          | 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             | 6.3%        | 1                | 12.5%       |
| STERILITY COMPROMISED  | 0           | 0        | 1                   | 1        | 0        | 0        | 0          | 0        | 0           | 0        | 1             | 6.3%        | 1                | 12.5%       |
| LABELING               | 0           | 0        | 4                   | 3        | 0        | 0        | 1          | 1        | 0           | 0        | 5             | 31.3%       | 4                | 50.0%       |
| STORAGE/DISTRIBUTION   | 2           | 0        | 1                   | 1        | 0        | 0        | 0          | 0        | 0           | 0        | 3             | 18.8%       | 1                | 12.5%       |
| MISCELLANEOUS          | 4           | 0        | 2                   | 1        | 0        | 0        | 0          | 0        | 0           | 0        | 6             | 37.5%       | 1                | 12.5%       |
| NON-REPORTABLE         | 0           | 0        | 0                   | 0        | 0        | 0        | 0          | 0        | 0           | 0        | 0             | 0.0%        | 0                | 0.0%        |
| <b>TOTAL</b>           | <b>6</b>    | <b>0</b> | <b>9</b>            | <b>7</b> | <b>0</b> | <b>0</b> | <b>1</b>   | <b>1</b> | <b>0</b>    | <b>0</b> | <b>16</b>     | <b>100%</b> | <b>8</b>         | <b>100%</b> |

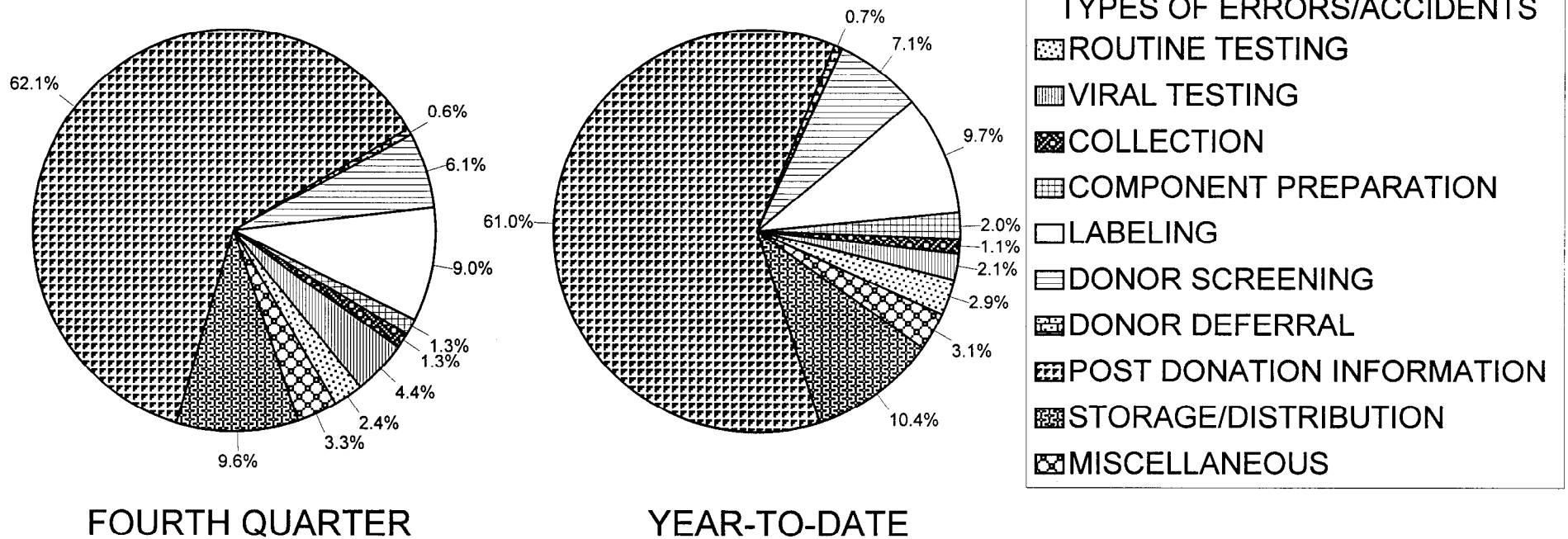
YEAR-TO-DATE - FY98  
NON-BLOOD MAUFACTURERS

| TYPE OF ERROR/ACCIDENT | DERIVATITVE |          | IN-VITRO DIAGNOSTIC |           | VACCINE  |          | ALLERGENIC |          | THERAPUETIC |          | 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             | 2.2%        | 1                | 6.7%        |
| STERILITY COMPROMISED  | 1           | 0        | 1                   | 1         | 0        | 0        | 0          | 0        | 2           | 0        | 4             | 8.9%        | 1                | 6.7%        |
| LABELING               | 1           | 0        | 8                   | 5         | 2        | 0        | 3          | 3        | 0           | 0        | 14            | 31.1%       | 8                | 53.3%       |
| STORAGE/DISTRIBUTION   | 4           | 0        | 3                   | 1         | 0        | 0        | 0          | 0        | 1           | 0        | 8             | 17.8%       | 1                | 6.7%        |
| MISCELLANEOUS          | 10          | 0        | 5                   | 4         | 1        | 0        | 0          | 0        | 0           | 0        | 16            | 35.6%       | 4                | 26.7%       |
| NON-REPORTABLE         | 1           | 0        | 1                   | 0         | 0        | 0        | 0          | 0        | 0           | 0        | 2             | 4.4%        | 0                | 0.0%        |
| <b>TOTAL</b>           | <b>17</b>   | <b>0</b> | <b>19</b>           | <b>12</b> | <b>3</b> | <b>0</b> | <b>3</b>   | <b>3</b> | <b>3</b>    | <b>0</b> | <b>45</b>     | <b>100%</b> | <b>15</b>        | <b>100%</b> |

# ERROR AND ACCIDENT REPORTS

## ALL BLOOD AND PLASMA ESTABLISHMENTS

### TOTAL REPORTS FY98



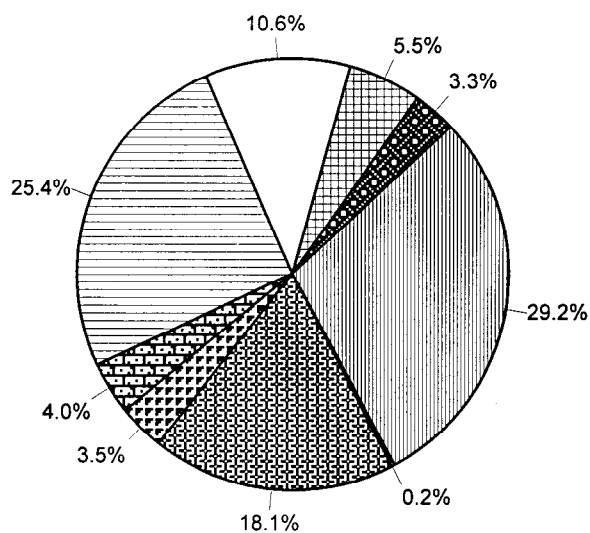
REPORTS RECEIVED FOURTH QUARTER (7/1/98 - 9/30/98) = 3533  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 9/30/98) = 13,187

# ERROR AND ACCIDENT REPORTS

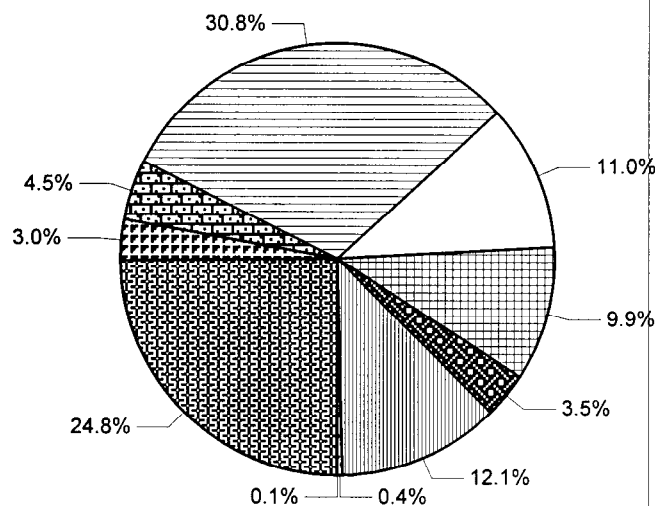
## ALL BLOOD AND PLASMA ESTABLISHMENTS

### POTENTIAL RECALLS

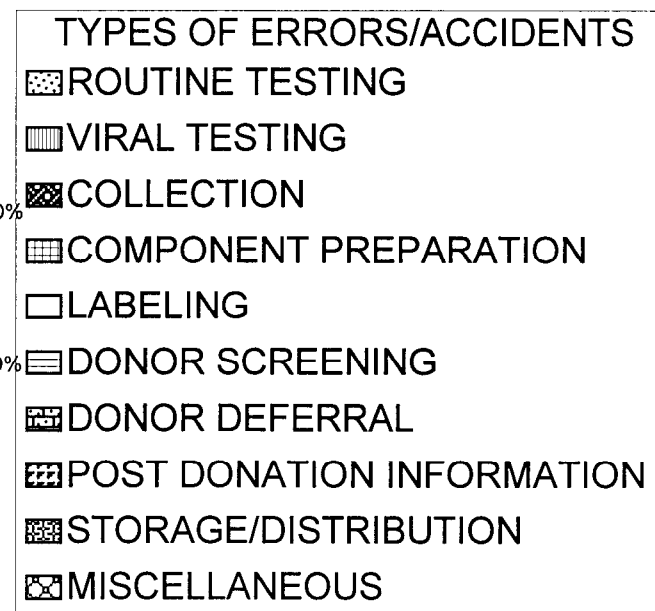
### FY98



FOURTH QUARTER



YEAR-TO-DATE

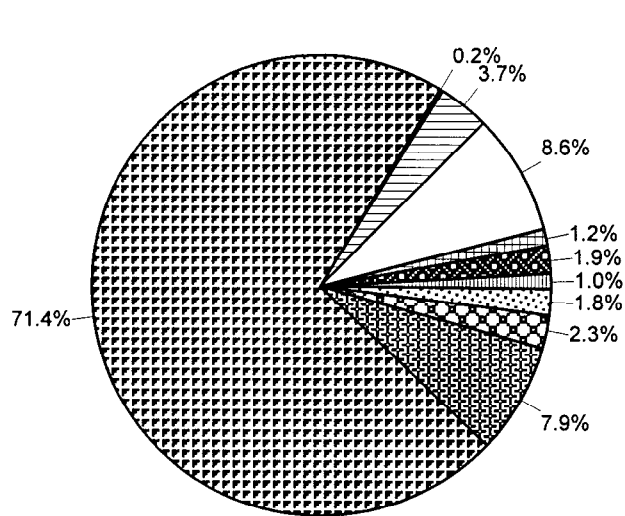


REPORTS RECEIVED FOURTH QUARTER (7/1/98 - 9/30/98) = 452  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 9/30/98) = 1677

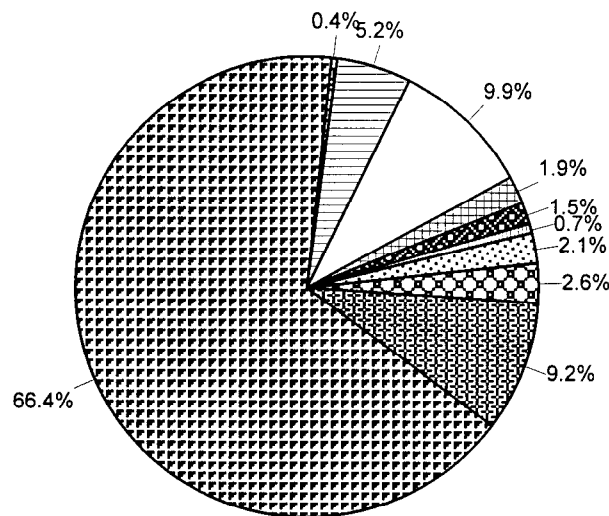
# ERROR AND ACCIDENT REPORTS

## AMERICAN RED CROSS

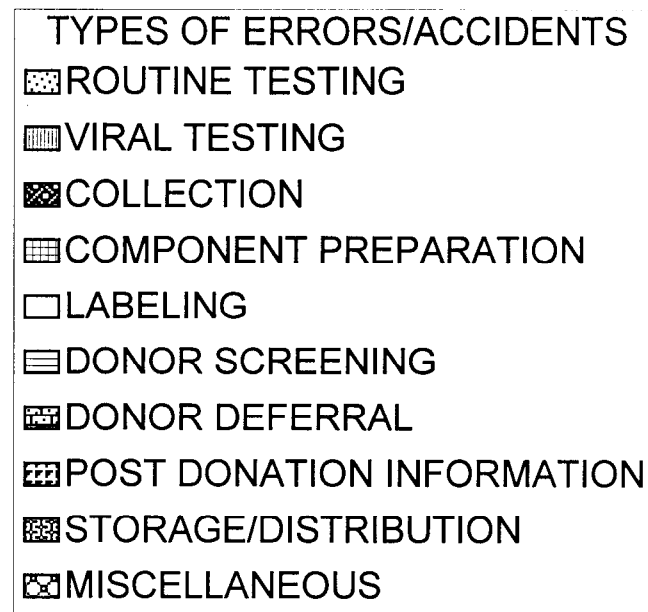
### FY98



FOURTH QUARTER



YEAR-TO-DATE

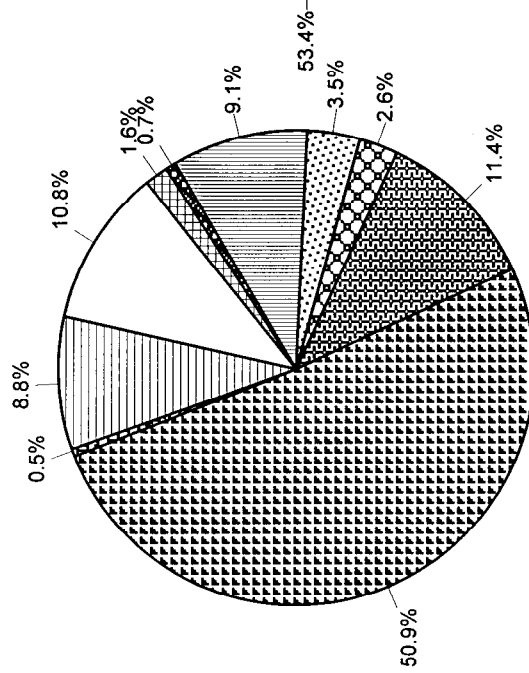


REPORTS RECEIVED FOURTH QUARTER (7/1/98 - 9/30/98) = 1720  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 9/30/98) = 6035

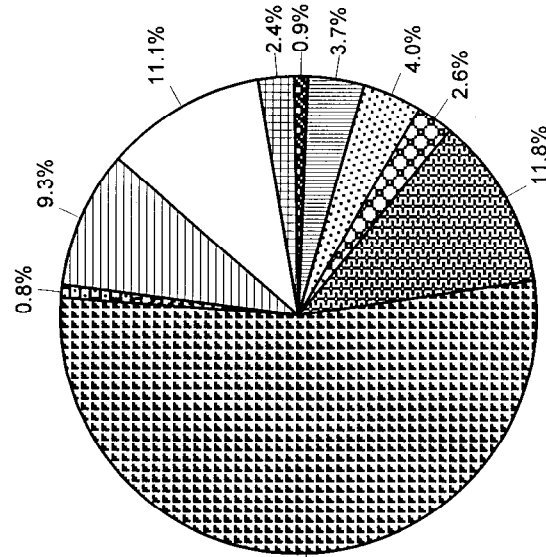


# ERROR AND ACCIDENT REPORTS NON-ARC LICENSED BLOOD BANKS

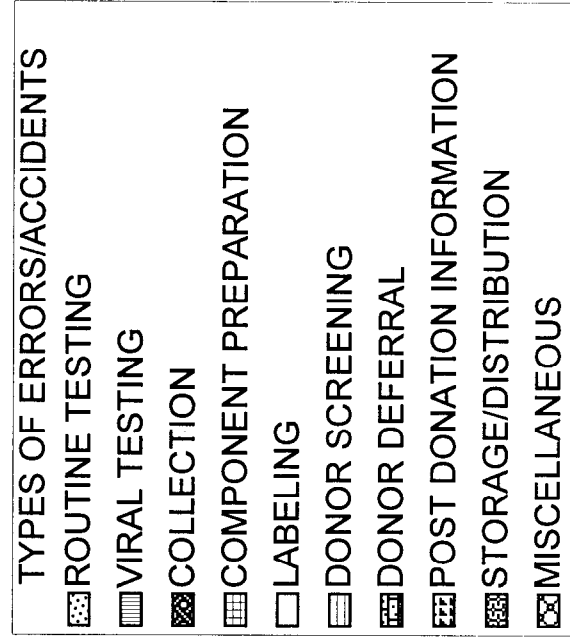
FY98



FOURTH QUARTER



YEAR-TO-DATE

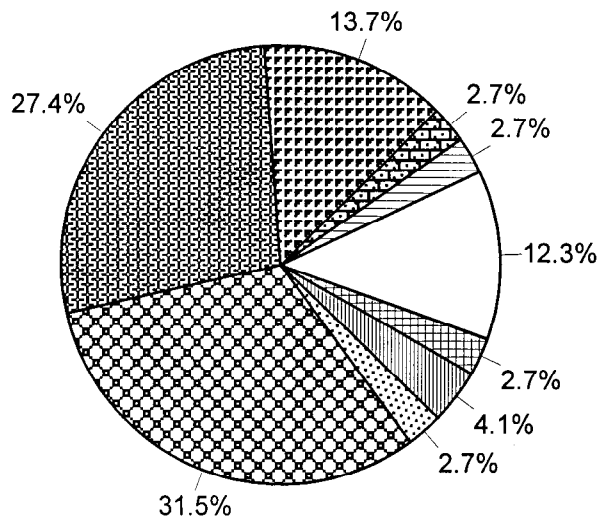


REPORTS RECEIVED FOURTH QUARTER (7/1/98 - 9/30/98) = 1480  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 9/30/98) = 5819

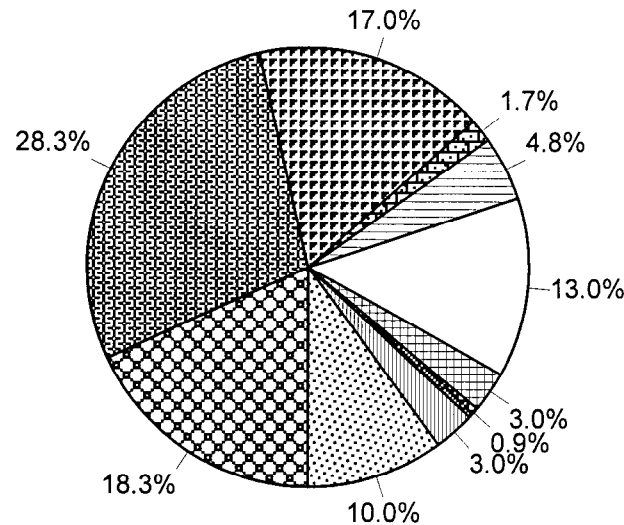
# ERROR AND ACCIDENT REPORTS

## UNLICENSED BLOOD BANKS

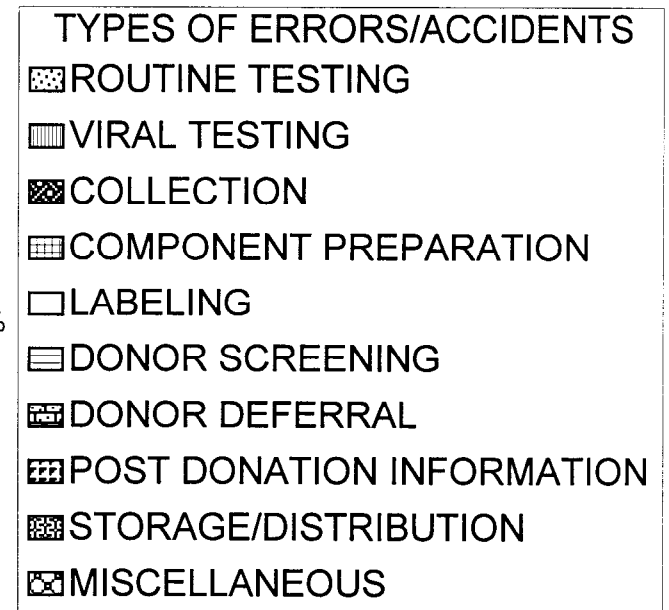
### FY98



FOURTH QUARTER



YEAR-TO-DATE

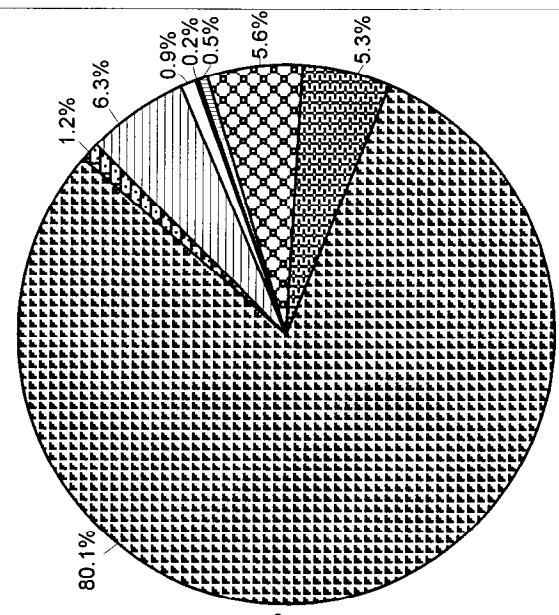
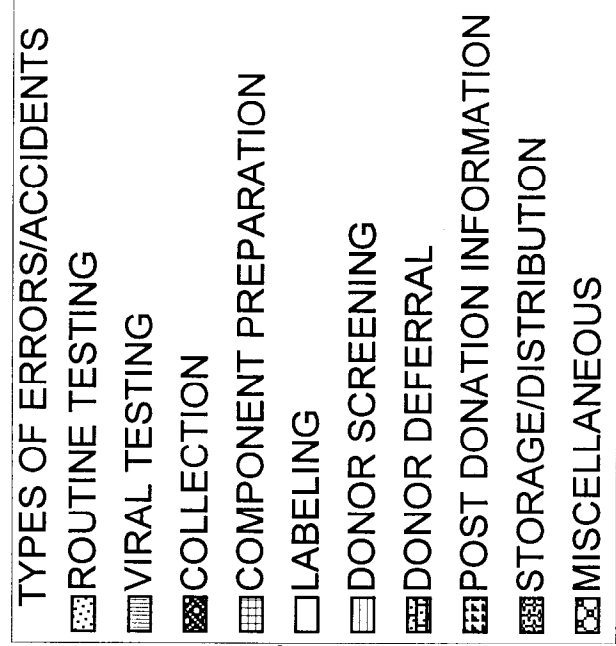


REPORTS RECEIVED FOURTH QUARTER (7/1/98 - 9/30/98) = 73 (7 REPORTS - TRANSFUSION SERVICES)  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 9/30/98) = 230 (19 REPORTS - TRANSFUSION SERVICES)

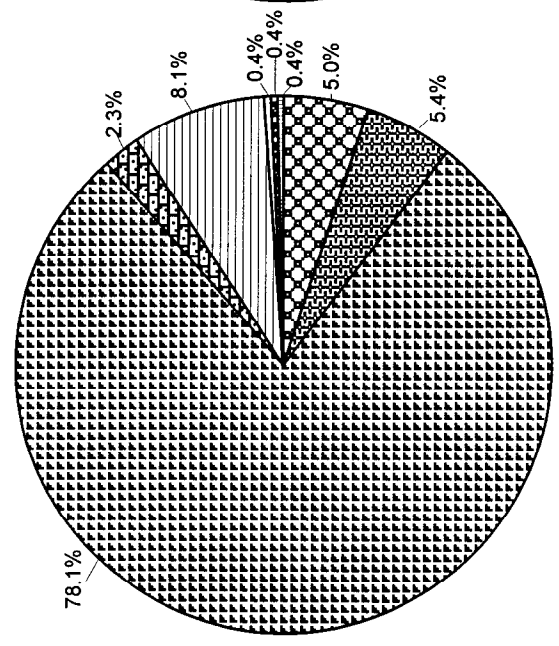
# ERROR AND ACCIDENT REPORTS

## PLASMA CENTERS

FY98



YEAR-TO-DATE

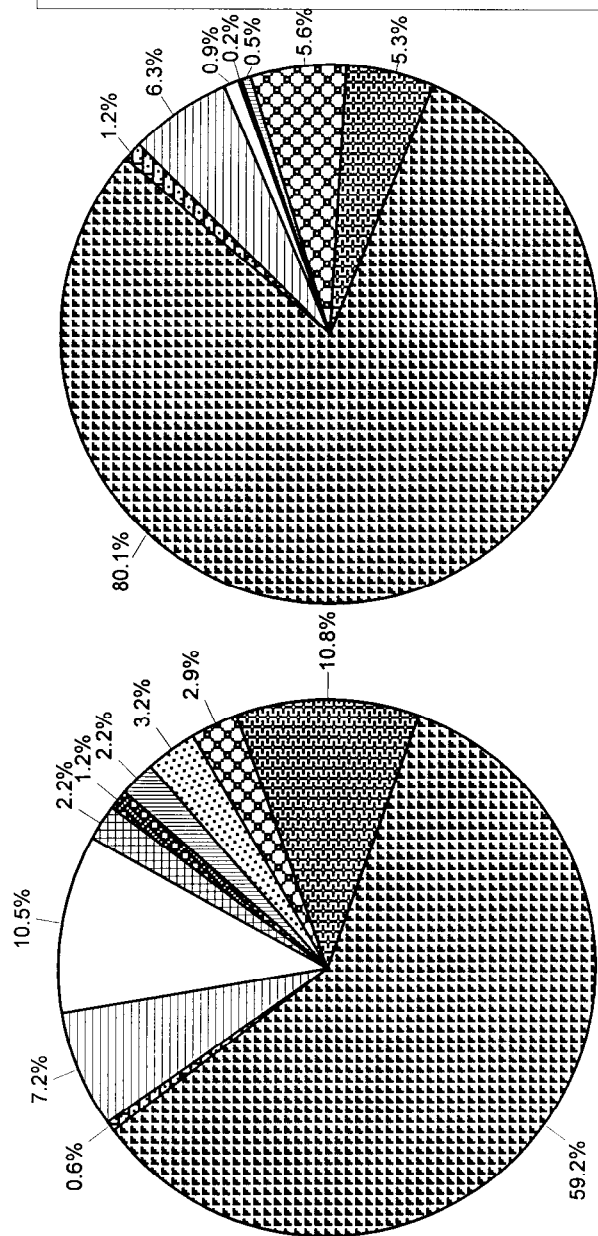


FOURTH QUARTER

REPORTS RECEIVED FOURTH QUARTER (7/1/98 - 9/30/98) = 260  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 9/30/98) = 1103

# ERROR AND ACCIDENT REPORTS BLOOD BANKS VERSUS PLASMA CENTERS

FY98 YEAR-TO-DATE



BLOOD BANKS

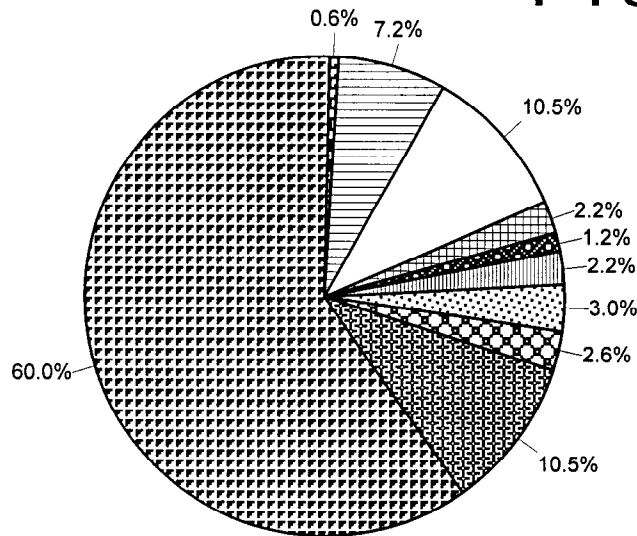
PLASMA CENTERS

REPORTS RECEIVED 10/1/97 - 9/30/98  
BLOOD BANKS = 12,084  
PLASMA CENTERS = 1103

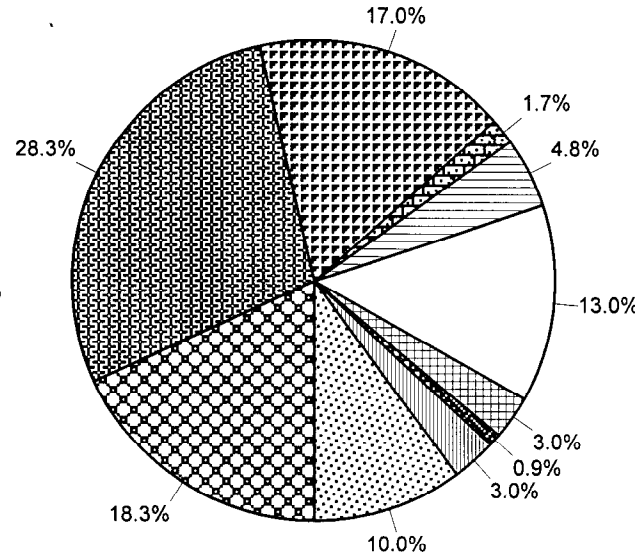
# ERROR AND ACCIDENT REPORTS

## BLOOD BANKS VERSUS PLASMA CENTERS

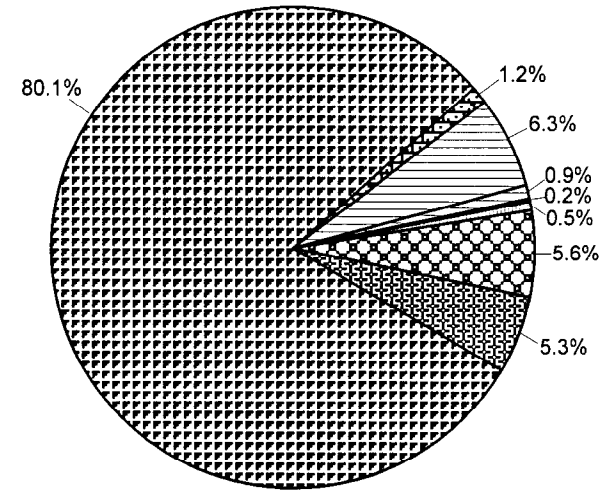
### FY98 YEAR-TO-DATE



LICENSED  
BLOOD BANKS



UNLICENSED  
BLOOD BANKS



PLASMA  
CENTERS

#### TYPES OF ERRORS/ACCIDENTS

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

REPORTS RECEIVED 10/1/97 - 9/30/98

LICENSED BLOOD BANKS = 11,854

UNLICENSED BLOOD BANKS = 230

PLASMA CENTERS = 1103

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

| TYPE OF ERROR/ACCIDENT    | NON-REPORTABLE | REPORTABLE  | TOTAL       | %NON-REPORTABLE |
|---------------------------|----------------|-------------|-------------|-----------------|
| ROUTINE TESTING           | 1              | 84          | 85          | 1.2%            |
| VIRAL TESTING             | 0              | 156         | 156         | 0.0%            |
| COLLECTION                | 18             | 27          | 45          | 40.0%           |
| COMPONENT PREPARATION     | 1              | 45          | 46          | 2.2%            |
| LABELING                  | 37             | 281         | 318         | 11.6%           |
| DONOR SCREENING           | 24             | 192         | 216         | 11.1%           |
| DONOR DEFERRAL            | 1              | 19          | 20          | 5.0%            |
| POST DONATION INFORMATION | 10             | 2184        | 2194        | 0.5%            |
| STORAGE/DISTRIBUTION      | 33             | 305         | 338         | 9.8%            |
| MISCELLANEOUS             | 111            | 4           | 115         | 96.5%           |
| <b>TOTAL</b>              | <b>236</b>     | <b>3297</b> | <b>3533</b> | <b>6.7%</b>     |

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

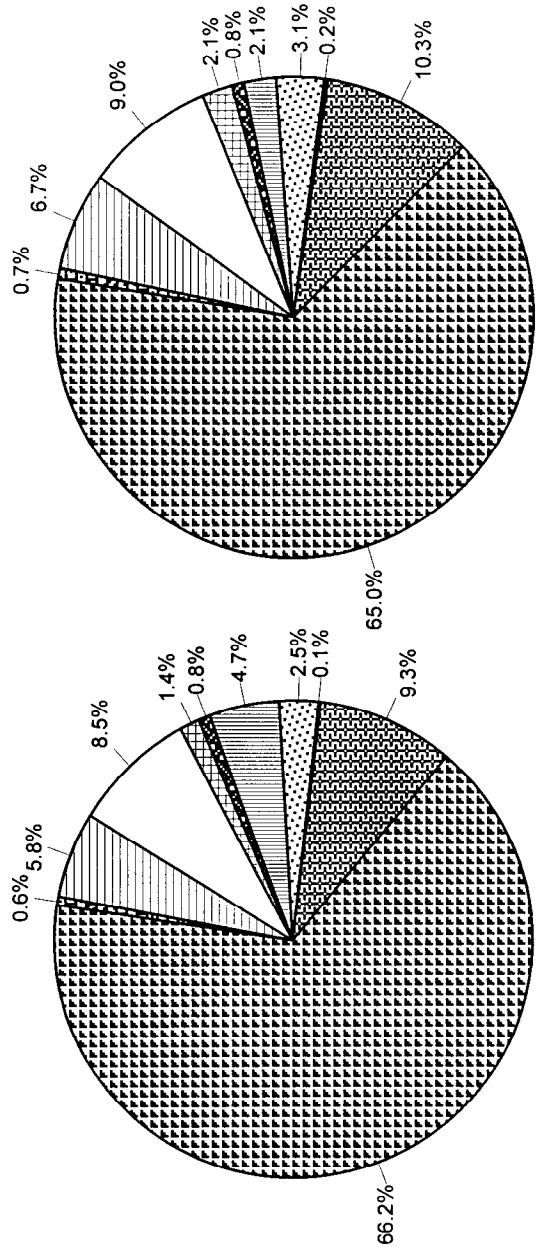
**FY98 - YEAR-TO-DATE  
BLOOD AND PLASMA ESTABLISHMENTS**

| TYPE OF ERROR/ACCIDENT    | NON-REPORTABLE | REPORTABLE   | TOTAL        | %NON-REPORTABLE |
|---------------------------|----------------|--------------|--------------|-----------------|
| ROUTINE TESTING           | 3              | 380          | 383          | 0.8%            |
| VIRAL TESTING             | 9              | 263          | 272          | 3.3%            |
| COLLECTION                | 48             | 101          | 149          | 32.2%           |
| COMPONENT PREPARATION     | 6              | 256          | 262          | 2.3%            |
| LABELING                  | 181            | 1101         | 1282         | 14.1%           |
| DONOR SCREENING           | 111            | 824          | 935          | 11.9%           |
| DONOR DEFERRAL            | 3              | 85           | 88           | 3.4%            |
| POST DONATION INFORMATION | 52             | 7986         | 8038         | 0.6%            |
| STORAGE/DISTRIBUTION      | 107            | 1261         | 1368         | 7.8%            |
| MISCELLANEOUS             | 381            | 29           | 410          | 92.9%           |
| <b>TOTAL</b>              | <b>901</b>     | <b>12286</b> | <b>13187</b> | <b>6.8%</b>     |

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

# ERROR AND ACCIDENT REPORTS ALL BLOOD AND PLASMA ESTABLISHMENTS REPORTABLE ERRORS/ACCIDENTS

FY98



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

YEAR-TO-DATE

FOURTH QUARTER

REPORTS RECEIVED FOURTH QUARTER (7/1/98 - 9/30/98) = 3297  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 9/30/98) = 12,286

## FY98 YEAR-TO-DATE

REPORTABLE ERRORS/ACCIDENTS - 12,286 (93.2% of total reports)

### Top Three Categories of Errors/Accidents:

Post Donation Information - 7986 (65.0% 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 - 1261 (10.3% 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 not documented
- Failure to quarantine a unit that was designated to be quarantined due to unsuitable medical history

Labeling - 1101 (9.0% 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
- Product labeled with incorrect ABO and/or Rh

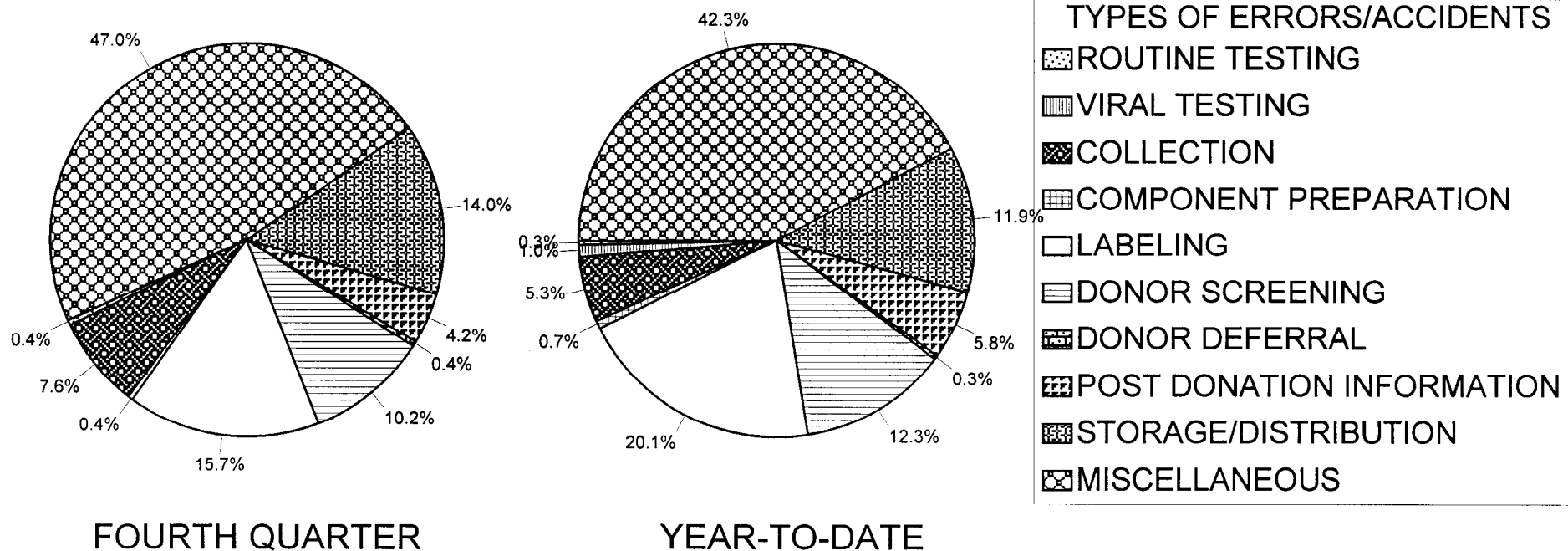


# ERROR AND ACCIDENT REPORTS

## ALL BLOOD AND PLASMA ESTABLISHMENTS

### NON-REPORTABLE ERRORS/ACCIDENTS

FY98



REPORTS RECEIVED FOURTH QUARTER (7/1/98 - 9/30/98) = 236  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 9/30/98) = 901

## FY98 YEAR-TO-DATE

NON-REPORTABLE ERRORS/ACCIDENTS - 901 (6.8% of total reports)

### Top Three Categories of Errors/Accidents:

Miscellaneous 381 ( 42.3% of non-reportables)

*\*Examples:*

- No products made available for distribution
- Recordkeeping error/accident - record is incorrect or not reviewed, testing and labeling acceptable
- Notification/retrieval procedures not followed (e.g., recall not performed within appropriate time)

Labeling - 181 (20.1% 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

Donor Suitability - 111 (12.3% of non-reportables)

*\*Example:*

- Donor did not meet acceptance criteria for time interval between donations
- Donor did not meet acceptance criteria for age
- Donor did not meet acceptance criteria for total protein or SPE

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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  
FOURTH 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%                           | 15         | 14                      | 8                 | 12            | 14           |
| 25%                           | 20         | 21                      | 15                | 16            | 20           |
| 50%                           | 29         | 33                      | 23                | 25            | 30           |
| 75%                           | 40         | 64                      | 37                | 55            | 46           |
| 90%                           | 49         | 128                     | 56                | 103           | 81           |
| # REPORTS                     | 1606       | 1394                    | 48                | 245           | 3293         |
| RANGE                         | 7-708      | 4-1009                  | 4-307             | 5-265         | 4-1009       |

ERROR AND ACCIDENT REPORTS  
RECEIVED 10/1/97 - 9/30/98

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

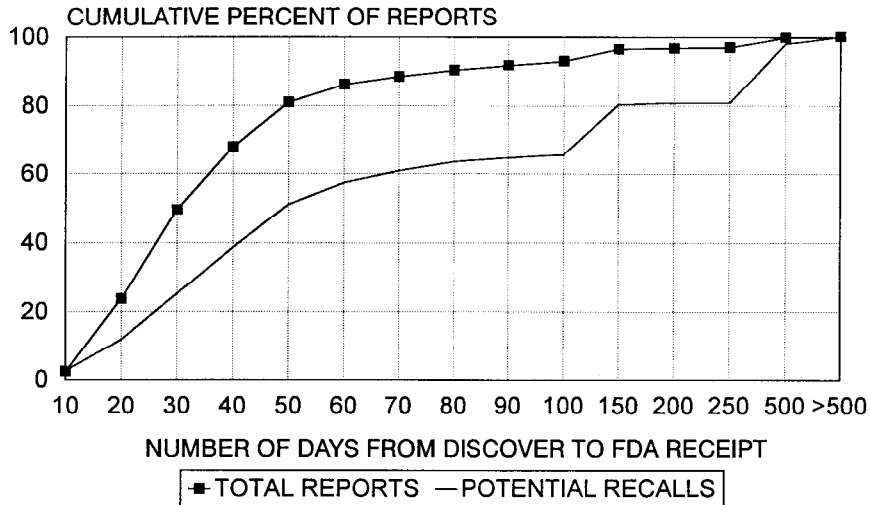
| CUMULATIVE PERCENT OF REPORTS | ARC (DAYS) | NON-ARC LICENSED (DAYS) | UNLICENSED (DAYS) | PLASMA (DAYS) | TOTAL (DAYS) |
|-------------------------------|------------|-------------------------|-------------------|---------------|--------------|
| 25%                           | 21         | 21                      | 14                | 18            | 21           |
| 50%                           | 29         | 34                      | 24                | 33            | 31           |
| 75%                           | 40         | 62                      | 48                | 71            | 47           |
| 90%                           | 48         | 119                     | 81                | 133           | 80           |
| # REPORTS                     | 5622       | 5437                    | 176               | 1046          | 12281        |
| RANGE                         | 5-708      | 4-1132                  | 4-727             | 3-559         | 3-1132       |

# ERROR AND ACCIDENT REPORTS

## REPORTING TIME

### ALL REPORTING BLOOD ESTABLISHMENTS

#### FOURTH QUARTER FY98



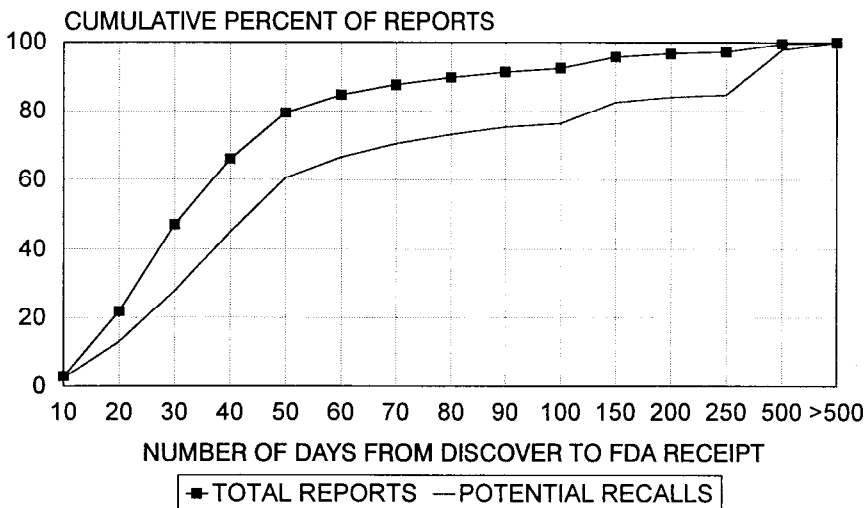
TOTAL REPORTS = 3293  
 POTENTIAL RECALLS = 452

# ERROR AND ACCIDENT REPORTS

## REPORTING TIME

### ALL REPORTING BLOOD ESTABLISHMENTS

#### YEAR -TO-DATE FY98



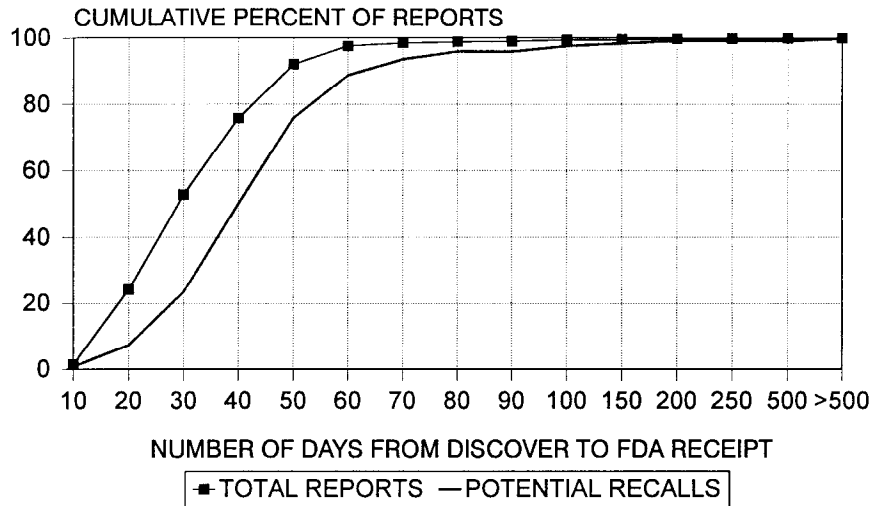
TOTAL REPORTS = 12,281  
 POTENTIAL RECALLS = 1685

# ERROR AND ACCIDENT REPORTS

## REPORTING TIME

### AMERICAN RED CROSS

FOURTH QUARTER FY98



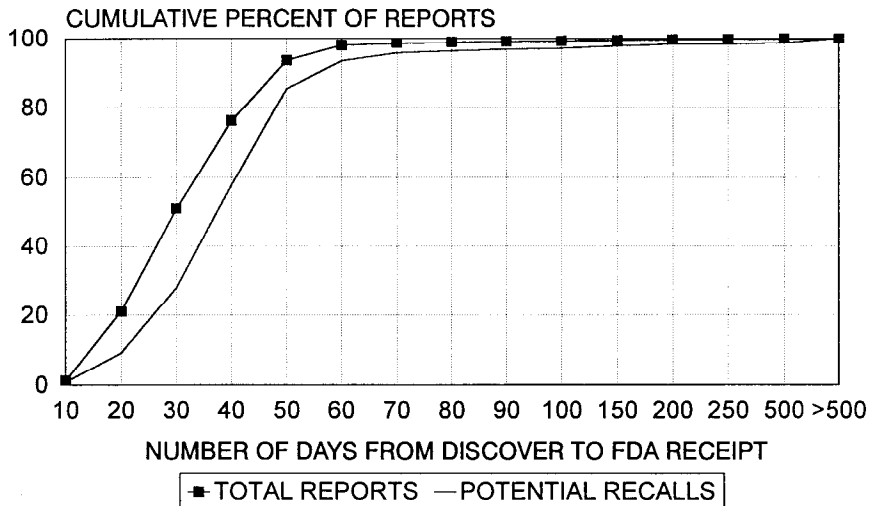
TOTAL REPORTS = 1606  
 POTENTIAL RECALLS = 124

# ERROR AND ACCIDENT REPORTS

## REPORTING TIME

### AMERICAN RED CROSS

YEAR-TO-DATE FY98



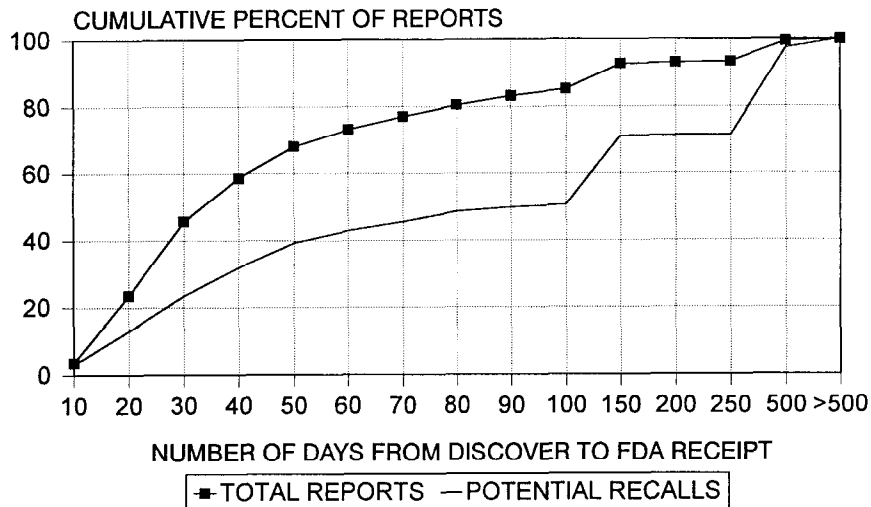
TOTAL REPORTS = 5622  
 POTENTIAL RECALLS = 528

# ERROR AND ACCIDENT REPORTS

## REPORTING TIME

### NON-ARC LICENSED BLOOD BANKS

FOURTH QUARTER FY98



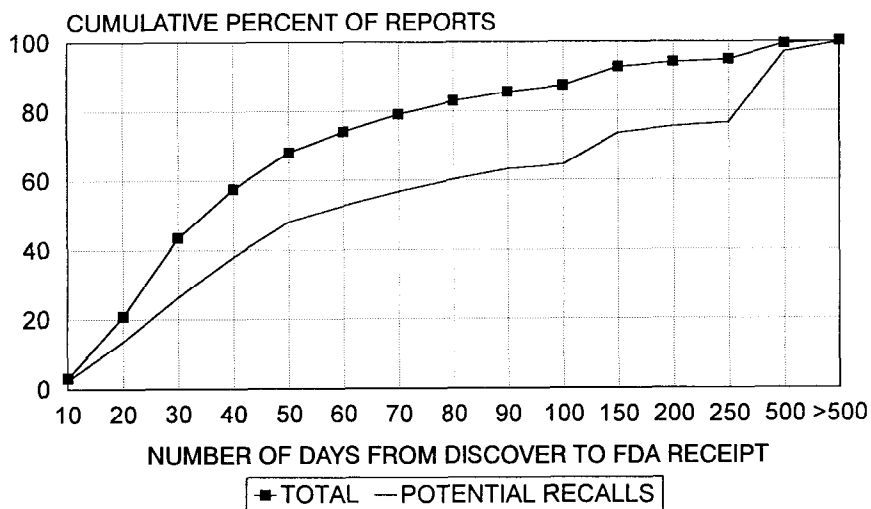
TOTAL REPORTS = 1394  
 POTENTIAL RECALLS = 299

# ERROR AND ACCIDENT REPORTS

## REPORTING TIME

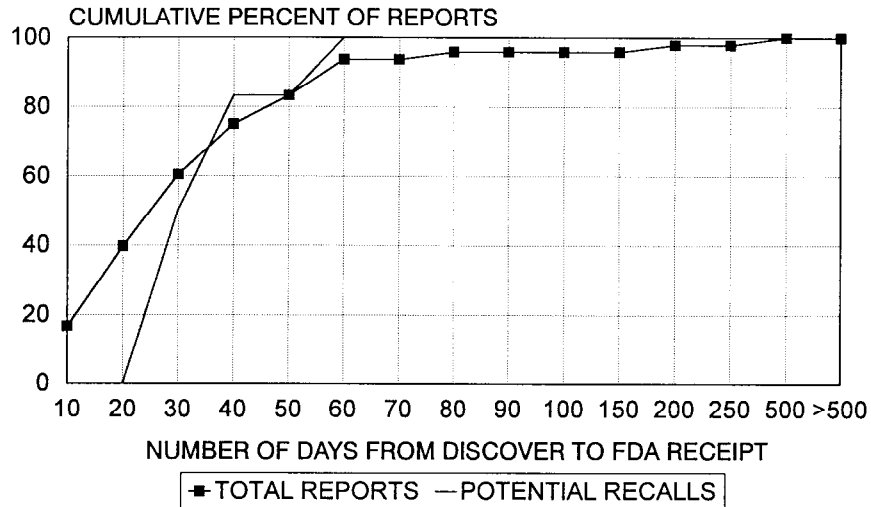
### NON-ARC LICENSED BLOOD BANKS

YEAR-TO-DATE FY98



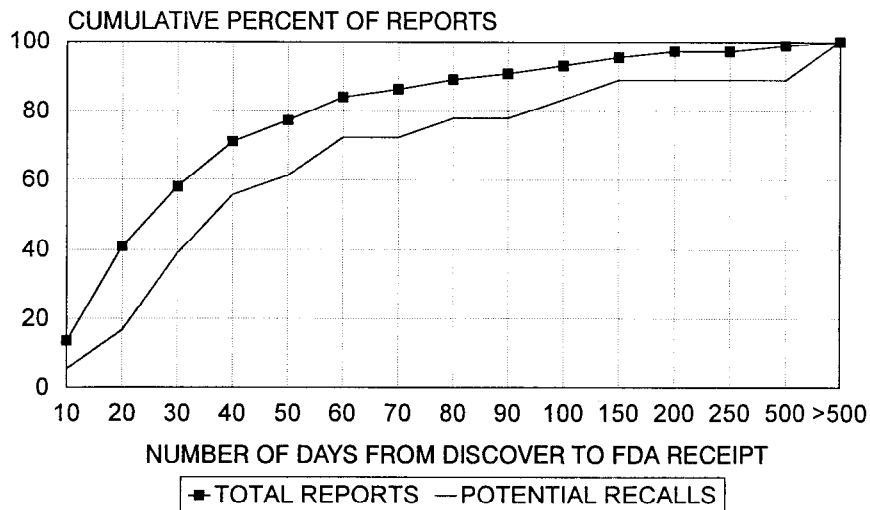
TOTAL REPORTS = 5437  
 POTENTIAL RECALLS = 1044

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



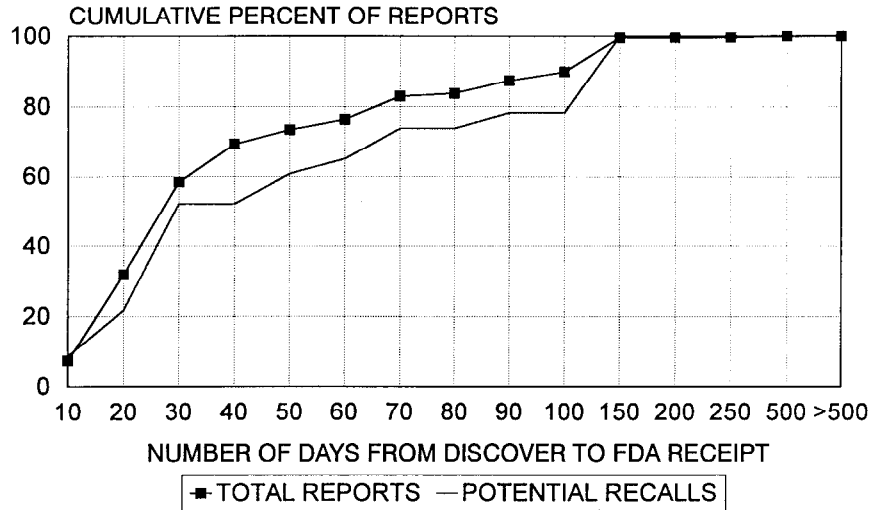
TOTAL REPORTS = 48  
POTENTIAL RECALLS = 6

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



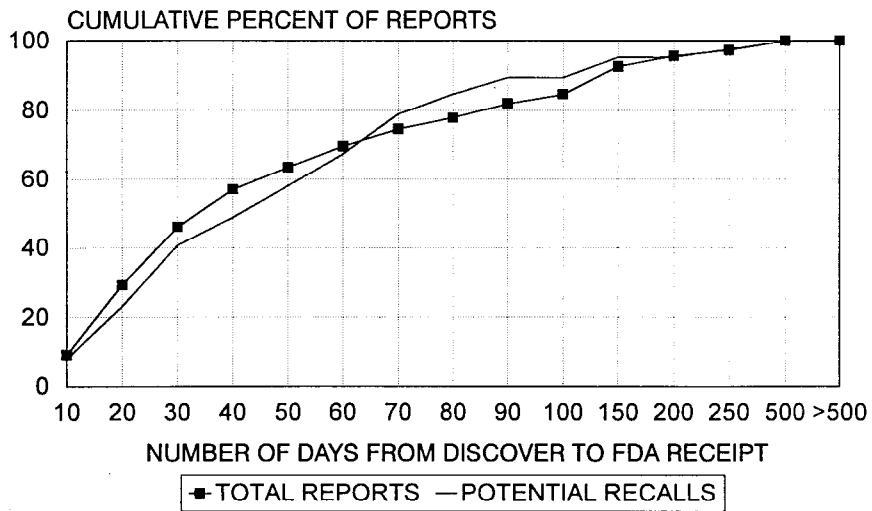
TOTAL REPORTS = 176  
POTENTIAL RECALLS = 18

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



TOTAL REPORTS = 245  
POTENTIAL RECALLS = 23

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



TOTAL REPORTS = 1046  
POTENTIAL RECALLS = 86

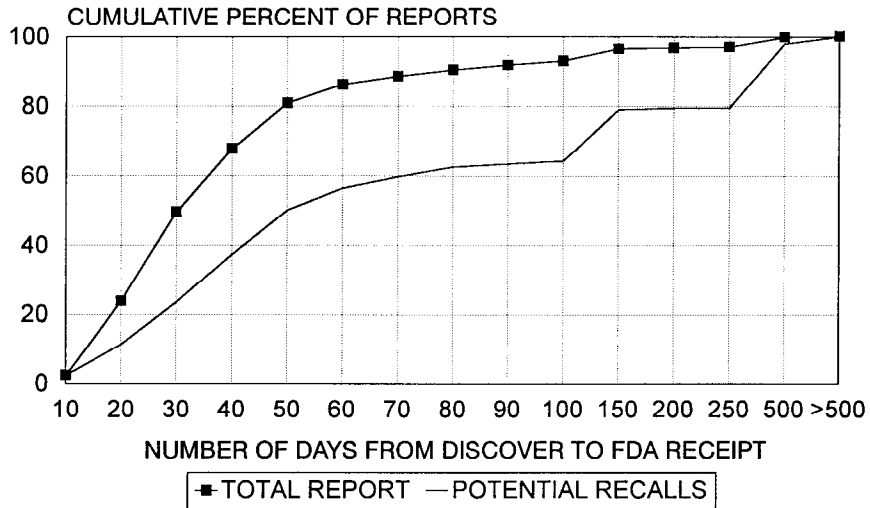


# ERROR AND ACCIDENT REPORTS

## REPORTING TIME

### ALL LICENSED BLOOD BANKS

FOURTH QUARTER FY98



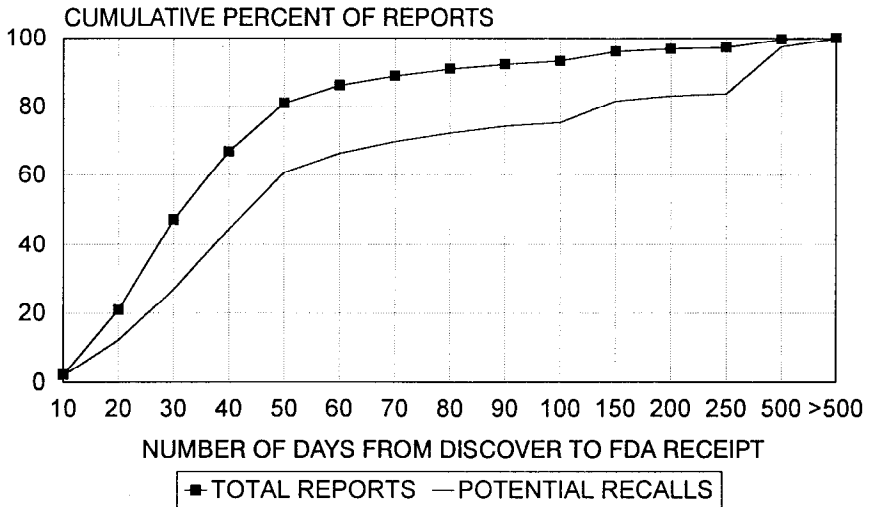
TOTAL REPORTS = 3000  
 POTENTIAL RECALLS = 423

# ERROR AND ACCIDENT REPORTS

## REPORTING TIME

### ALL LICENSED BLOOD BANKS

YEAR-TO-DATE FY98



TOTAL REPORTS = 11,059  
 POTENTIAL RECALLS = 1,572