M E M O R A N D U M

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

DATE: FEB 2 2 2000

FROM: Sharon O'Callaghan, CSO,
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Office of Compliance and Biologics Quality

SUBJECT: Error and Accident Reports - Summary for First Quarter FY2000

TO: Director, Division of Inspections and Surveillance (HFM-650)
Office of Compliance and Biologics Quality

Between October 1, 1999 and December 31, 1999, the Division of Inspections and Surveillance received 4274 error and accident reports from biological product manufacturers. Blood and plasma establishments submitted 4236 reports and non-blood manufacturers submitted 38 reports. There were 311 (7.3%) 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, 131 (3.1%) 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 errors and accidents submitted by blood and plasma establishments and by non-blood manufacturers. In addition, a table and graphs representing reportable errors and accidents submitted by blood and plasma establishments 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 that CBER received the report.

Attachments

Attachments

1 - Table - Total Error/Accident Reports
    All Reporting Establishments
2 - Tables - Types of Errors/Accidents
    Blood and Plasma Establishments
        Total Reports, Potential Recalls
3 - Pie charts - All Blood and Plasma Establishments
    Total Reports, Potential Recalls
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    Non-Blood Manufacturers
16 – Tables (2 pages) Detailed Listing of Errors/Accidents for Non-Blood Manufacturers
17 - Pie chart - Types of Errors/Accidents
    Non-Blood Manufacturers

FIRST QUARTER – FY2000

ALL REPORTING ESTABLISHMENTS

	NUMBER OF REPORTING ESTABLISHMENTS	TOTAL REPORTS RECEIVED	POTENTIAL RECALLS
BLOOD/PLASMA MANUFACTURERS			
Licensed Blood Establishments	113*	3692	281
Unlicensed Blood Establishments	22	27	3
Transfusion Services	9	9	0
Plasma Centers	175	508	25
SUB-TOTAL	*319*	*4236*	*309*
NON-BLOOD MANUFACTURERS			
Blood Derivative Manufacturers	5	6	0
In-Vitro Diagnostic Manufacturers	3	7	0
Vaccine Manufacturers	4	5	0
Allergenics Manufacturers	5	16	2
Therapeutic Manufacturers	4	4	0
SUB-TOTAL	*21*	*38*	*2*
TOTAL	**340**	**4274**	**311**

*Number of license holders; may be one establishment or multiple establishments operating under one license.

The following tables and pie charts show the type of errors and accidents reported by blood and plasma establishments:

FIRST QUARTER – FY2000

BLOOD AND PLASMA ESTABLISHMENTS

TOTAL ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	Licensed Establishments	Unlicensed Establishments	Transfusion Services	Plasma Centers	TOTAL	
POST DONATION INFORMATION	2725	3	0	459	3187	75.2%
STORAGE/DISTRIBUTION	307	5	2	10	324	7.6%
DONOR SCREENING	219	1	0	24	244	5.8%
LABELING	221	4	2	2	229	5.4%
ROUTINE TESTING	77	3	5	0	85	2.0%
MISCELLANEOUS	47	4	0	8	59	1.4%
COLLECTION	36	3	0	0	39	0.9%
COMPONENT PREPARATION	30	0	0	0	30	0.7%
VIRAL TESTING	17	3	0	2	22	0.5%
DONOR DEFERRAL	13	1	0	3	17	0.4%
TOTAL	3692	27	9	508	4236	100%

POTENTIAL RECALLS

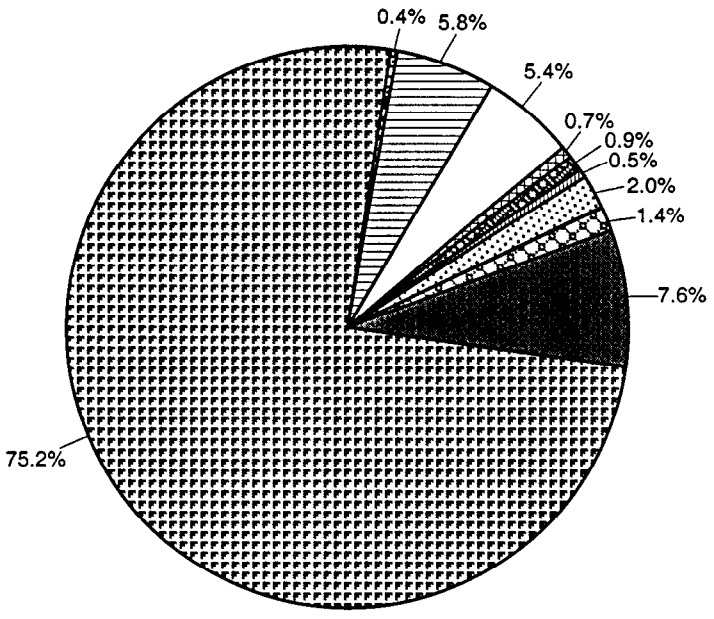
TYPE OF ERROR/ACCIDENT	Licensed Establishments	Unlicensed Establishments	Transfusion Services	Plasma Centers	TOTAL	
DONOR SCREENING	121	0	0	14	135	43.7%
STORAGE/DISTRIBUTION	43	1	0	6	50	16.2%
POST DONATION INFORMATION	29	0	0	2	31	10.0%
LABELING	28	1	0	0	29	9.4%
COMPONENT PREPARATION	23	0	0	0	23	7.4%
COLLECTION	20	0	0	0	20	6.5%
DONOR DEFERRAL	10	0	0	2	12	3.9%
VIRAL TESTING*	5	1	0	1	7	2.3%
ROUTINE TESTING	2	0	0	0	2	0.6%
MISCELLANEOUS	0	0	0	0	0	0.0%
TOTAL	281	3	0	25	309	100.0%

* There was a decrease in the number of testing errors and accidents reported from 17.4% (300) in FY99 to 2.3% (7) in FY2000. In FY99, one establishment, that is no longer operating as a licensed establishment, submitted 267 reports.

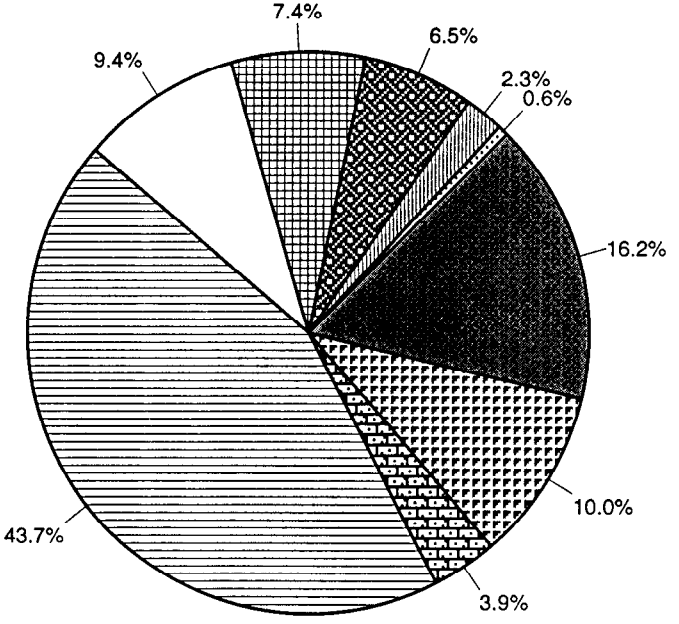
ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

FY2000



TOTAL REPORTS



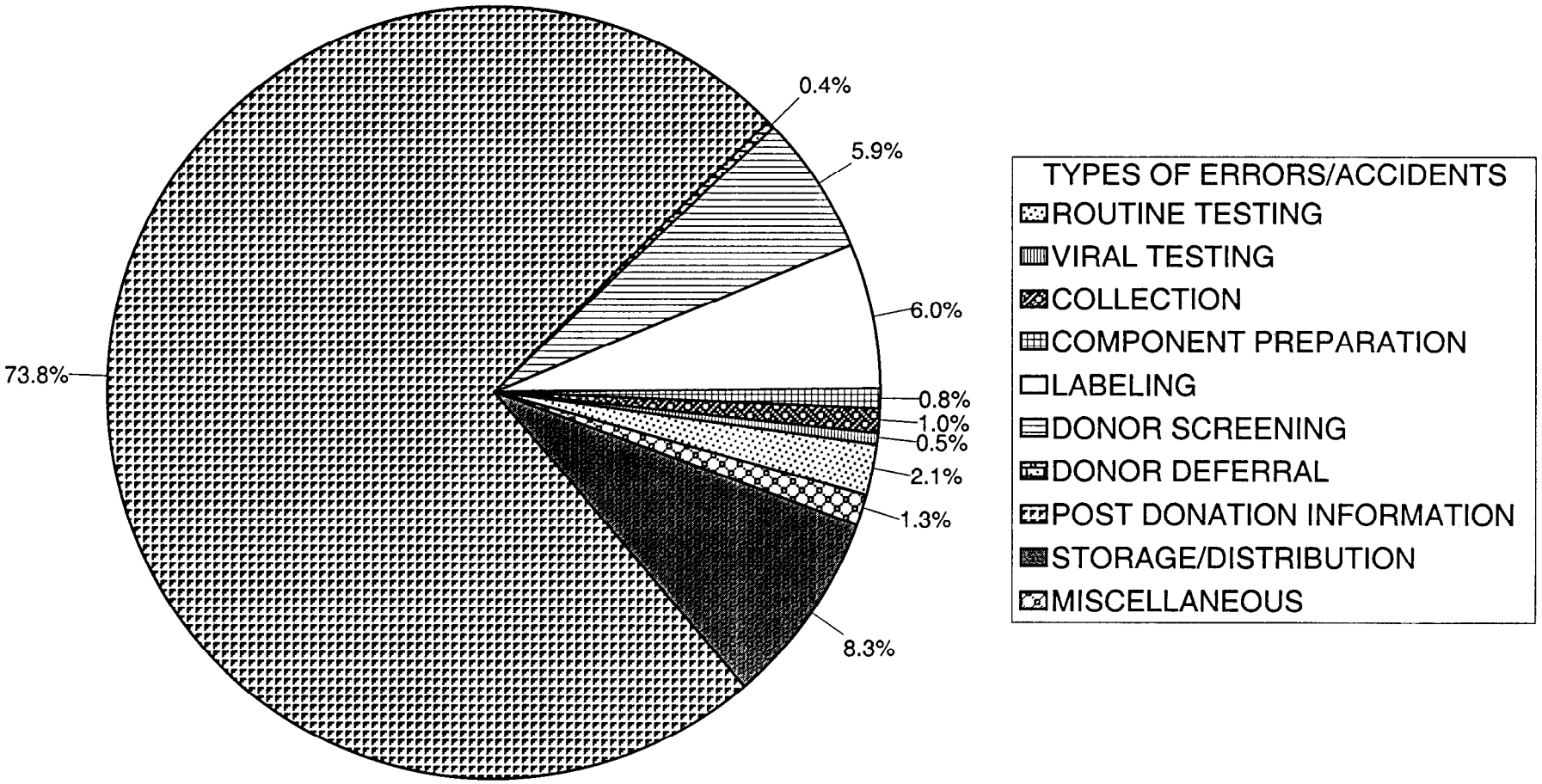
POTENTIAL RECALL

TYPES OF ERRORS/ACCIDENTS

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

TOTAL REPORTS RECEIVED (10/1/99 - 12/31/99) = 4236
POTENTIAL RECALLS = 309

ERROR AND ACCIDENT REPORTS
LICENSED BLOOD ESTABLISHMENTS
FY2000

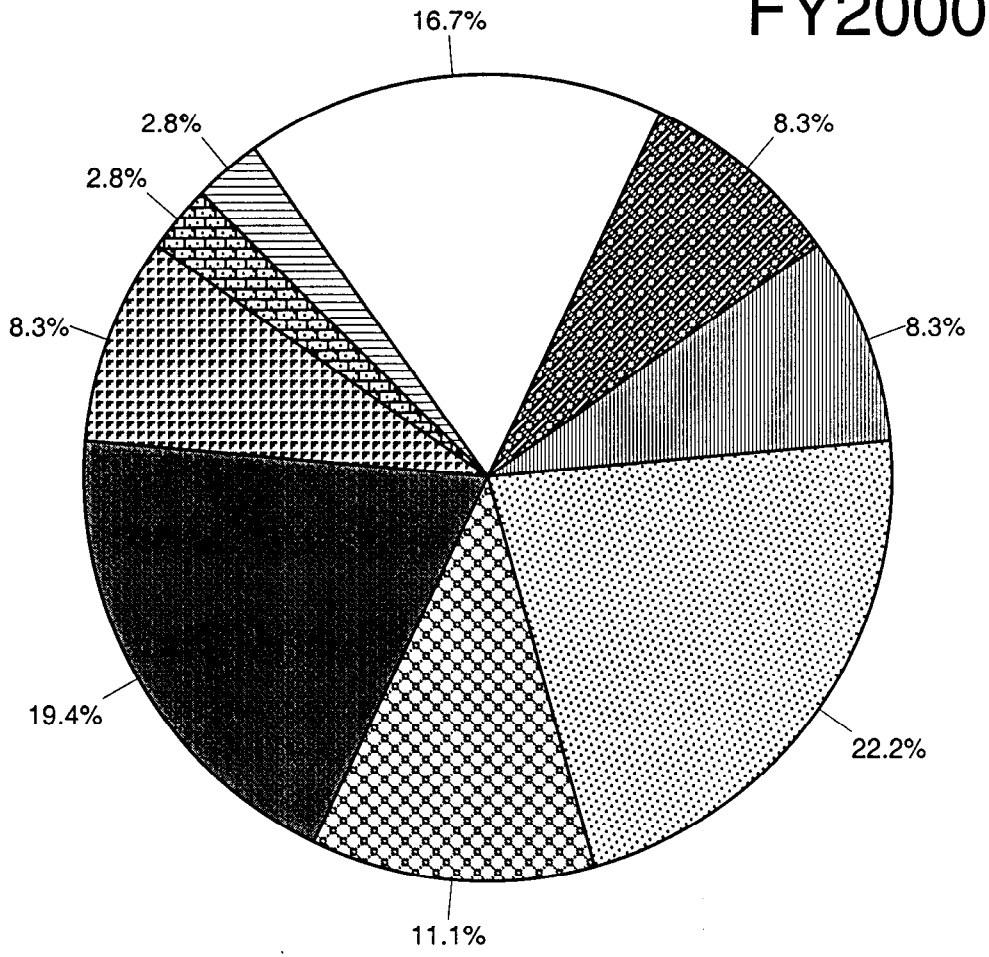


REPORTS RECEIVED (10/1/99 - 12/31/99) = 3692

ERROR AND ACCIDENT REPORTS

UNLICENSED BLOOD ESTABLISHMENTS

FY2000

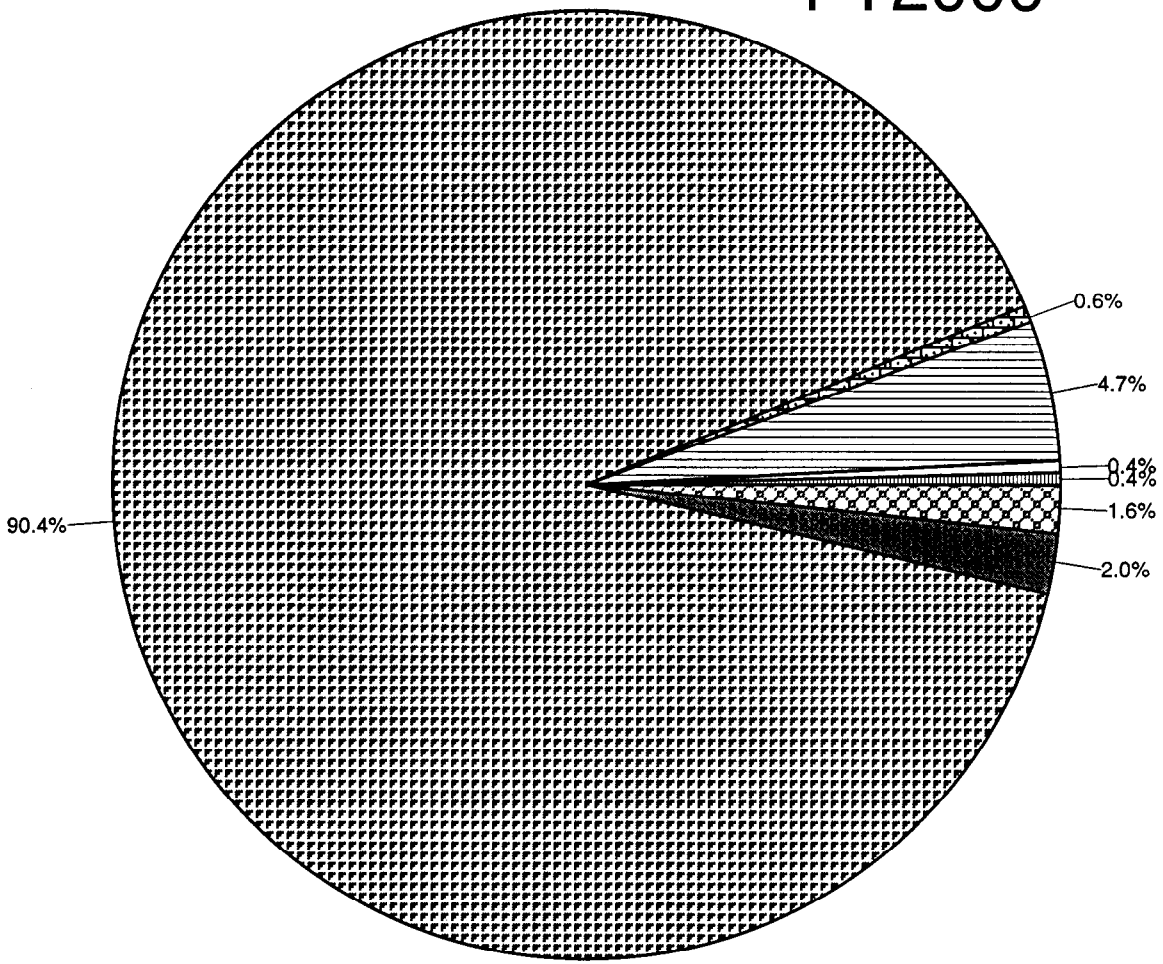


REPORTS RECEIVED (10/1/99 - 12/31/99) = 36
UNLICENSED BLOOD BANKS = 27; TRANSFUSION SERVICES = 9

ERROR AND ACCIDENT REPORTS

PLASMA CENTERS

FY2000



REPORTS RECEIVED (10/1/99 - 12/31/99) = 508

FIRST QUARTER – FY2000

BLOOD AND PLASMA ESTABLISHMENTS

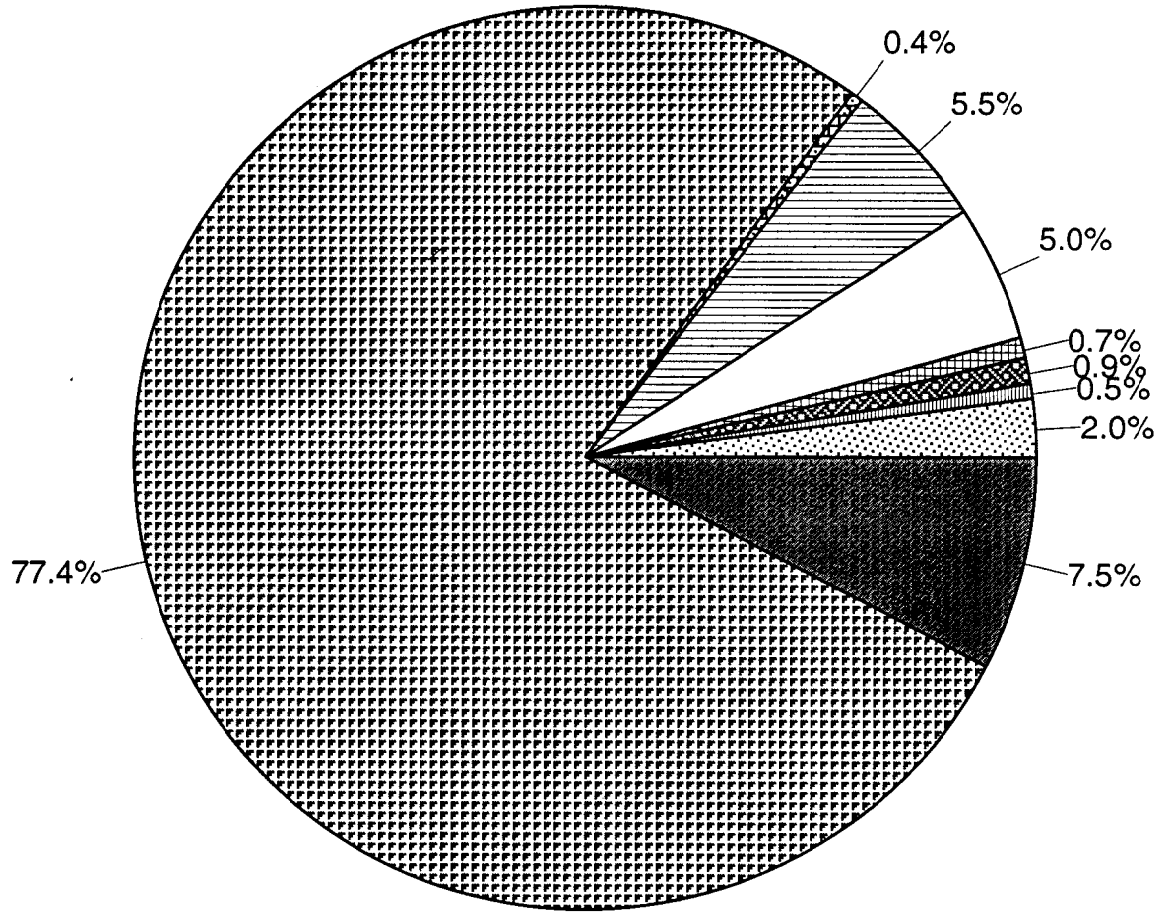
TYPE OF ERROR/ACCIDENT	REPORTABLE	NON-REPORTABLE	TOTAL	%REPORTABLE
POST DONATION INFORMATION	3178	9	3187	99.7%
STORAGE/DISTRIBUTION	310	14	324	95.7%
DONOR SCREENING	225	19	244	92.2%
LABELING	204	25	229	89.1%
ROUTINE TESTING	83	2	85	97.6%
COLLECTION	38	1	39	97.4%
COMPONENT PREPARATION	30	0	30	100.0%
VIRAL TESTING	22	0	22	100.0%
DONOR DEFERRAL	17	0	17	100.0%
MISCELLANEOUS	1	58	59	1.7%
TOTAL	4108	128	4236	97.0%

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

REPORTABLE ERRORS/ACCIDENTS

FY2000



TOTAL REPORTS RECEIVED (10/1/99 - 12/31/99) = 4236
REPORTABLE ERRORS/ACCIDENTS = 4108 (97.0%)

FY2000
Reports Received 10/1/99 – 12/31/99

REPORTABLE ERRORS/ACCIDENTS - 4108 (97.0% of total reports)

Top Three Categories of Errors/Accidents:

Post Donation Information - 3178 (77.4% of reportables)
**Examples:*
Information provided post donation:
- Donor traveled to a malarial endemic area
- Donor received tattoo, earpiercing, accidental needlestick, or transfusion
- Donor had a history of cancer
- [1]Donor traveled to UK between 1980 and 1996 (nvCJD risk)
- Donor became ill after donation,
  not related to hepatitis, HIV, HTLV-I, sexually transmitted diseases or cold/flu symptoms

[1] *As a result of implementation of the guidance document published August 17, 1999, there was a significant increase in the number of post donation information reports related to CJD risk factors. The guidance recommended deferral of donors who have spent six months or more cumulatively in the United Kingdom from 1980 through 1996. There were 125 reports submitted in FY-99 and 296 reports in FY2000 related to risk factors for CJD. Of the 296 reports received in FY2000, 263 were related to donors who provided information of travel to the United Kingdom.*

Storage/Distribution - 310 (7.5% of reportables)
**Examples:*
- Release of product that contained clots or would not flow through a filter
- Failure to quarantine unit, reason for quarantine:
  - outdated product
  - product QC unacceptable or not documented
  - product specification not met
  - collection time extended, discrepant or not documented
  - unit released prior to resolution of discrepancy
  - unsuitable medical history
- Product was shipped or stored at incorrect temperature

Donor Screening – 225 (5.5% of reportables)
**Examples:*
- Donor provided information that warranted deferral, but donor was not deferred
- Donor record incomplete or incorrect
- Donor deferral list not checked

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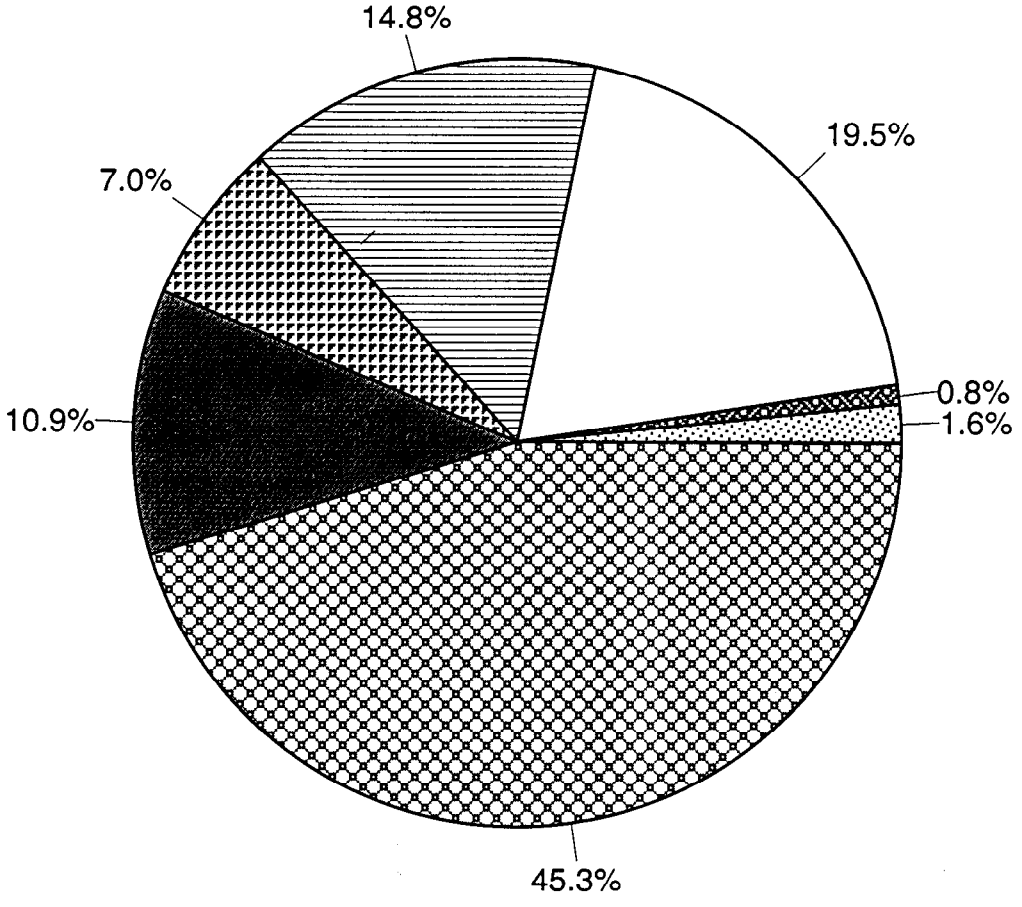
*Examples of errors and accidents represent at least 50% of reports in each category.

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

NON-REPORTABLE ERRORS/ACCIDENTS

FY2000



TOTAL REPORTS RECEIVED (10/1/99 - 12/31/99) = 4236
REPORTABLE ERRORS/ACCIDENTS = 128 (3.0%)

FY2000
Reports Received 10/1/99 – 12/31/99

NON-REPORTABLE ERRORS/ACCIDENTS - 128 (3.0% of total reports)

Top Three Categories of Errors/Accidents:

Miscellaneous 58 (45.3% of non-reportables)
**Examples:*

- No products made available for distribution
- Recordkeeping error/accident - record is incorrect or not reviewed, testing and labeling acceptable

Labeling - 25 (19.5% of non-reportables)
**Examples:*

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

Donor Suitability 19 (14.8% of non-reportables)
**Examples:*

- Donor did not meet acceptance criteria for time interval between donations (e.g., <56 days from previous donation)
- Donor did not meet acceptance criteria for Age

*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 CBER received reports from the blood and plasma establishments. The evaluation of timeliness is limited to only reports that met the threshold for reporting.

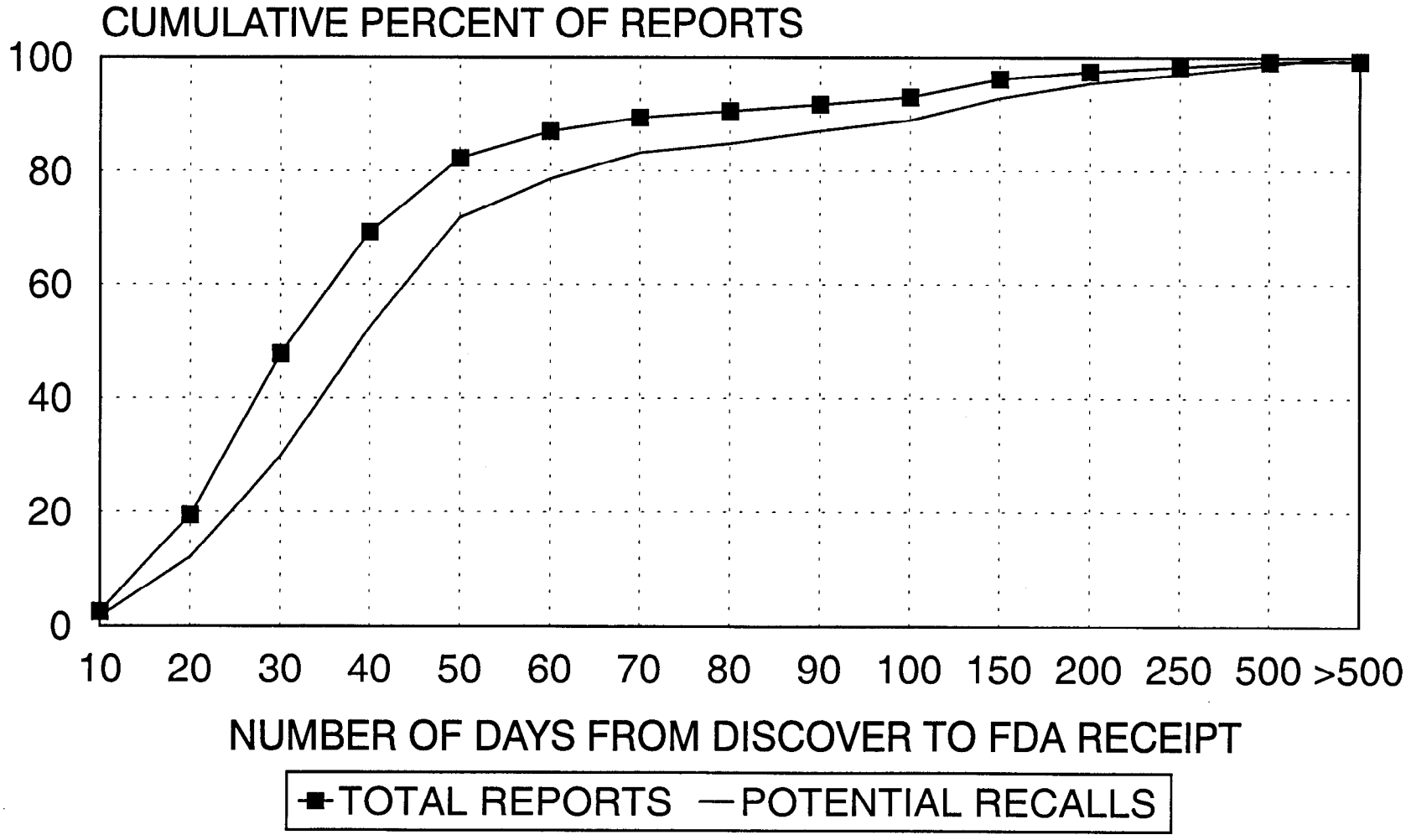
ERROR AND ACCIDENT REPORTS
FIRST QUARTER – FY2000

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

BLOOD AND PLASMA ESTABLISHMENTS

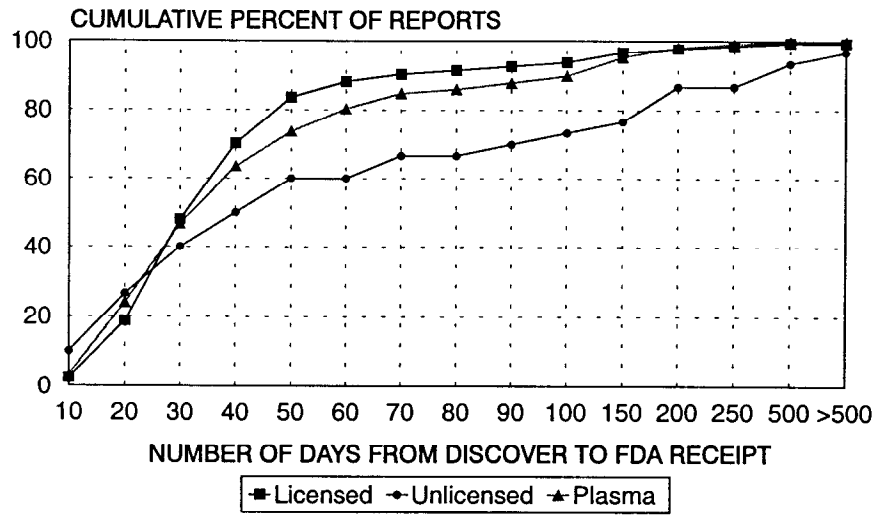
CUMULATIVE PERCENT OF REPORTS	LICENSED (Days)	UNLICENSED (Days)	PLASMA (Days)	TOTAL (Days)
10%	16	8	13	16
25%	22	20	20	22
50%	30	40	32	31
75%	43	148	52	44
90%	68	265	102	75
# REPORTS	3579	30	499	4108
RANGE	3-1133	7-566	4-424	3-1133

ERROR AND ACCIDENT REPORTS
REPORTING TIME
ALL REPORTING BLOOD AND PLASMA ESTABLISHMENTS
FY-2000



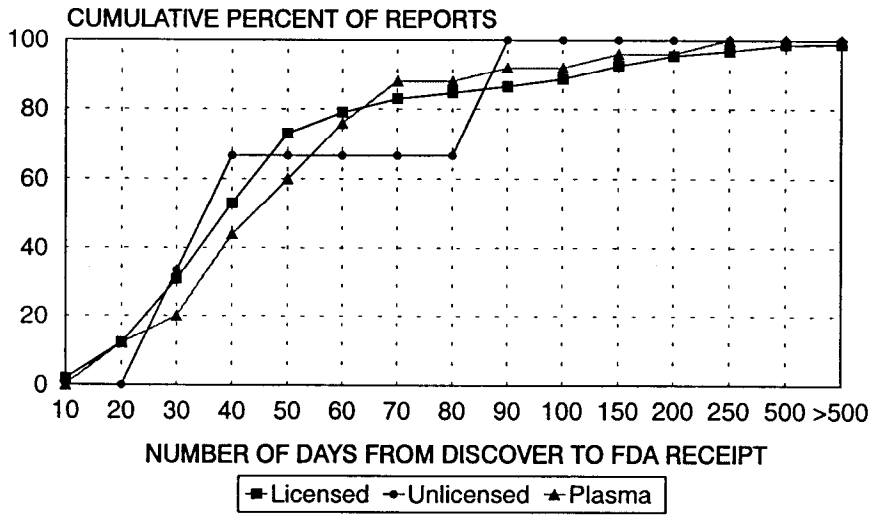
TOTAL REPORTS = 4108
POTENTIAL RECALLS = 309

ERROR AND ACCIDENT REPORTS
REPORTING TIME
TOTAL REPORTS
FY-2000



TOTAL REPORTS = 4108
LICENSED BLOOD EST.= 3579; UNLICENSED BLOOD EST. = 30; PLASMA CENTERS = 499

ERROR AND ACCIDENT REPORTS
REPORTING TIME
POTENTIAL RECALLS
FY-2000



TOTAL REPORTS = 309
LICENSED BLOOD EST.= 281; UNLICENSED BLOOD EST. = 3; PLASMA CENTERS = 25

The following tables and pie charts show the type of errors and accidents reported by non-blood manufacturers:

FIRST QUARTER – FY2000

NON-BLOOD MAUFACTURERS

	DERIVATITVE		IN-VITRO DIAGNOSTIC		ALLERGENIC		THERAPUETIC		VACCINE		TOTAL		POTENTIAL RECALL	
TYPE OF ERROR/ACCIDENT	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	0	0	0	0	4	0	1	0	0	0	5	13.2%	0	0.0%
LABELING	0	0	5	0	5	1	0	0	2	0	12	31.6%	1	50.0%
STORAGE/DISTRIBUTION	1	0	1	0	1	0	1	0	0	0	4	10.5%	0	0.0%
PROCESSING	1	0	0	0	4	1	1	0	3	0	9	23.7%	1	50.0%
MISCELLANEOUS	3	0	1	0	0	0	1	0	0	0	5	13.2%	0	0.0%
NOT REPORTABLE	*1*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*0*	*0*	*3*	*7.9%*	*0*	*0.0%*
TOTAL	6	0	7	0	16	2	4	0	5	0	38	100%	2	100%

NON-BLOOD MANUFACTURERS

DERIVATIVES

ERROR/ACCIDENT	#REPORTS
STORAGE/DISTRIBUTION	***1***
Product released prior to CBER approval - expiration of CBE submission	1
PROCESSING	***1***
Source material unsuitable for processing due to donor previously deferred	1
MISCELLANEOUS	***3***
Glass defects	1
Water for Injection system was not sampled	1
Factor IX Complex tested positive for HAV RNA during final container PCR testing, associated products released	1
NON-REPORTABLE	***1***
Product labeled with missing/incorrect facility identifiers - product acceptable	1
TOTAL	***6***

IN-VITRO DIAGNOSTICS

ERROR/ACCIDENT	#REPORTS
LABELING	***5***
Package insert incorrect	3
Product label incorrect	1
Lot number missing or incorrect and expiration date also missing	1
STORAGE/DISTRIBUTION	***1***
Product released prior to completion of required testing	1
MISCELLANEOUS	***1***
Wrong vial replaced in the 11-cell panel, due to hemolysis	1
TOTAL	***7***

NON-BLOOD MANUFACTURERS

ALLERGENICS

ERROR/ACCIDENT	#REPORTS
STERILITY COMPROMISED	***4***
Stoppers contaminated with endotoxin	1
Loose seal resulted in a leaking vial	1
A piece of rubber from the stopper found in vial	1
Contents leaking out	1
LABELING	***5***
Potency not on vial label	2
Product label incorrect	1
Lot number missing/incorrect	1
Concentration missing or incorrect	1
STORAGE/DISTRIBUTION	***1***
Sterility test cultures may not have been incubated for 14 days at 30-35 degrees C before products released	1
MISCELLANEOUS	***4***
Computer calculation error for preparation of extract	1
Error in correcting calculation error resulted in concentration of 835 PNU/ml instead of 1000 PNU/ml	1
Formula change	1
PNU value incorrectly entered into the computer	1
NON-REPORTABLE	***2***
Product labeled with missing/incorrect weight or volume; product acceptable	1
Illegible expiration date	1
TOTAL	***16***

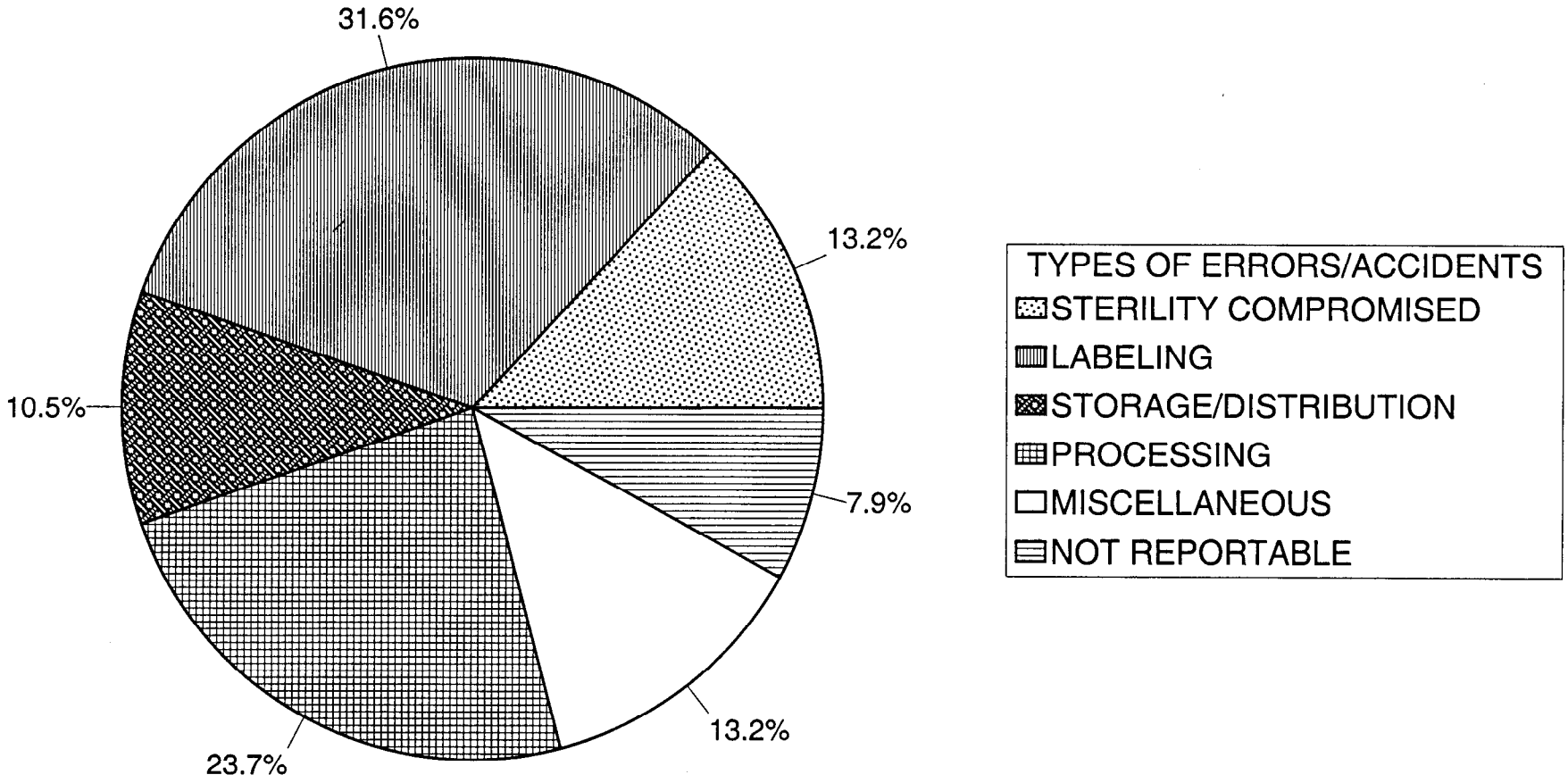
THERAPEUTICS

ERROR/ACCIDENT	#REPORTS
STERILITY COMPROMISED	***1***
Reovirus contamination of EPO concentrated diafiltered medium	1
STORAGE/DISTRIBUTION	***1***
Product shipped or stored at incorrect temperature	1
PROCESSING	***1***
Product specification not met	1
MISCELLANEOUS	***1***
Stability testing failed	1
TOTAL	***4***

VACCINES

ERROR/ACCIDENT	#REPORTS
LABELING	***2***
Package insert incorrect	2
PROCESSING	***3***
Product specification not met	3
TOTAL	***5***

ERROR AND ACCIDENT REPORTS
NON-BLOOD MANUFACTURERS
FY2000



TOTAL REPORTS RECEIVED (10/1/99 - 12/31/99) = 38
REPORTABLE ERRORS/ACCIDENTS = 35; NON-REPORTABLE ERRORS/ACCIDENTS = 3