DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
6000 Metro Drive, Suite 101 **Baltimore, Maryland 21215**	FEI NUMBER: 1000123507
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED **TO: Ramesh Thadani, Executive Vice President and Chief Executive Officer**	
FIRM NAME American National Red Cross/Biomedical Services	STREET ADDRESS 1616 Fort Myer Drive
CITY, STATE AND ZIP CODE Arlington, Virginia 22209	TYPE OF ESTABLISHMENT INSPECTED National Headquarters of a Licensed Blood Bank

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

INADEQUATE INVESTIGATION OF EMPLOYEE ALLEGATIONS OF SIGNIFICANT RECORDKEEPING IRREGULARITIES:

Biomedical Headquarters (BHQ) has failed to properly evaluate all employee allegations of significant record keeping irregularities and take corrective action to prevent recurrence.

1. On 10/6/00, the Vice President of Quality Assurance (QA) submitted a potential system problem. The records of the system problem indicate the issue was "non-concurrent documentation and falsification of records-cases have been identified..." On 10/16/00, this issue was assigned system problem # 511. On 3/27/01, the system problem was closed by the Chief Operating Officer as being "isolated instances" not meeting the definition of a system problem. The cases reviewed involved four reports from National Testing Laboratories (NTLs) and eight reports from the ARC regions. Examples are as follows: following the erroneous release of two plasma products in one region, one employee reported being asked to sign as a second reviewer for a shipment she had not physically counted and that employees were "cutting corners" to increase the amount of product packed. Another region reported that an employee took the health history from the donor, failed to document the reason for deferral of the donor and then discarded the health history record when the reason for deferral could not be recalled.

2. After closure of the system problem #511 and without BHQ taking any system-wide corrective action allegations of significant record keeping irregularities continued to be received. From December 2001 to January 2002, there were at least three reports of records not reflecting the actual work performed or non concurrent record keeping in the NTLs:

a) In December 2001, a report from one NTL stated that 28 products had been labeled with hemoglobin S results although no test results were recorded on the testing worksheet. This worksheet was also reviewed and signed by two other employees including quality control staff. The report indicates that the quality assurance officer in the NTL stated there was a "culture to hide problems" and "there is a pervasive attitude that the staff can clean problems up so they can never be found."

b) In January 2002, an employee in an NTL reported that another employee "over incubated the antibody plates but had not recorded the correct times on the worksheet." The investigation revealed the employee who witnessed the problem had reported a similar incident to the supervisor; however, that incident was not investigated at the time. The employee reported fearing retaliation if she was seen reporting a problem to the supervisor.

c) In January 2002, the records indicate there was an "Investigation of Falsification of NAT Test Records." During that investigation, one employee reported that "verification is to be performed concurrently when possible but due to staffing levels workload, this does not always occur."

3. A special audit was conducted in August 2001 when the region's management notified regional QA of a "possible falsification of records." The report states "The fact that only the cumulative loss records were altered would have an affect on donor safety and not product quality." All staff interviewed "verified they found documents which were

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Linda S. Mattingly Stephanie J. Wesley	Mary J. Carden, Investigator Linda S. Mattingly, Investigator Stephanie J. Wesley, Investigator	12/20/02

changed and their initials had been forged in the changed documents." The report indicates one employee stated "He was afraid of losing his job and he knew if he brought a complaint up to the top, he would have been found out and then set up to be fired."

4. ARC uses a system known as the "Hotline" as another means in which an employee can report concerns or problems related to the manufacturing of blood products, donor and patient safety as well as human resource matters. The following "hotline" records describe reports from ARC employees of allegations of significant record keeping irregularities:

[redacted]: The records of investigation provided by ARC indicate one employee was "terminated for falsification of records on 5/31/02" and a second employee was forced to resign due to "falsification of records – backdated records."

[redacted]: The records of investigation provided by ARC indicate the employee reported that a cooler was allowed to go 12 degrees above temperature but it was never documented. "The cooler was re-cooled and then reported at the proper temperature."

[redacted]: The records of investigation provided by ARC indicate the issues investigated were: "caller states nurses are using out of date test tubes and falsifying documents;" "caller suggests falsification of documents should be ground for termination;" and "caller states acting supervisor instructs employees to falsify documents in order to hide mistakes."

[redacted]: The records of investigation provided by ARC indicate the caller stated the team manager "completed a donors Blood Donation Record (BDR)" by placing the confidential unit exclusion form on the BDR for the donor.

[redacted]: The records of investigation provided by ARC indicate an employee was instructed "to alter the donors history to indicate the initial pulse rate to be 98 beats per minute instead of 104 beats per minute." The records also state "it was determined that you instructed other staff members on the blood drive to keep this to themselves and not allow this deviation to surface."

[redacted]: The records of investigation provided by ARC indicate an employee reported that management at an apheresis center has the employees continue with the collections even though the machine alarms indicate a donor's platelet count is too low to continue or complete the donation. It was also reported that employees are told not to document this alarm type in the alarm log.

[redacted]: The records of investigation provided by ARC indicate a supervisor changed the information on training records because he failed to properly release a new employee to perform Anti-HBc testing at an NTL. The record also states "caller stated … falsified documentation in the red book and the trainee roster which he/she stated is a violation of FDA regulations."

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INADEQUATE INVESTIGATION OF POTENTIAL PROBLEMS WITH PRACTICES RELATED TO DONOR DEFERRAL RATES

5. Several regions implemented policies tracking donor deferral rates for health history reasons by employee, tracking hematocrit deferral rates by employee and closely observing trained employees. The "hotline" reports indicate a potential problem presented by current management practices related to donor deferral rates. However, BHQ failed to determine whether this is a system problem and to take corrective action to prevent recurrence:

[redacted]: The records of investigation provided by ARC indicate a report was received that donors with low hematocrits were being accepted. Results were being re-read "into acceptance" by a second individual.

[redacted]: The records of investigation provided by ARC indicate an employee reported that managers were instructed to verify the hematocrit readings made by staff. Region reported managers were instructed to review the number of hematocrit deferrals by each staff member and if the number for any employee was "excessive" to observe the employee.

[redacted]: The records of investigation provided by ARC indicate an employee asked how to lower her history deferral rate without jeopardizing the safety of the blood supply and without providing "false information." The employee stated it was the regions policy to hold deferrals against collection employees on their performance evaluations. The employee believes this would seem to foster wrongdoing on the part of the collection staff. Collection staff might be tempted to lie about donors' histories or qualifications to donate so they will be allowed to donate when in fact they should be deferred. The employee also stated that collection staff might destroy blood donation records for donors they had to defer, in order to lower their deferral rates.

[redacted]: The records of investigation provided by ARC indicate an employee reported that they are being reprimanded when their deferral rate is too high and are instructed by management to improve by decreasing the number of deferrals.

[redacted]: The records of investigation provided by ARC indicate employees have reported that since converting only to the finger stick to determine iron levels, the deferral rate has dramatically increased and they are being blamed for this increase. Employees report that management is consistently monitoring them.

[redacted]: The records of investigation provided by ARC indicate an employee reported that management informed them that their deferral rates are too high, especially for low iron readings. Employee reported that they are required to have a nurse oversee a second test to check hemoglobin levels.

[redacted]: The records of investigation provided by ARC indicate an employee reported that management is instructing employees to accept allogeneic donors with iron levels under 38 percent.

INVESTIGATION OF SUSPECTED POST TRANSFUSION HEPATITIS (fatality):

6. Procedures do not require a thorough investigation of the occurrence of a clinically significant infection or

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infectious disease that occurs in a recipient of a blood product that could have resulted from transfusion and for which another, more likely, cause is not apparent (Consent Decree III.B.14). ARC's procedures and policies indicate a donor is only considered "implicated" in a SPTIHBV (Suspect Post Transfusion Infection of Hepatitis B) if the donor had abnormal hepatitis test result(s) or was already in the donor deferral registry for hepatitis related reasons. ARC's procedures only require review of actual testing records, associated quality control records, and re-contact of the donor for additional testing and verification of health history unless ARC considers the donor "implicated."

7. SPTHEP Case [redacted] investigated by the Greater Chesapeake and Potomac Region, was a follow up to a post transfusion hepatitis fatality that occurred at a hospital on November 19, 2001. The recipient (now deceased) received two units of Red Blood Cells manufactured by ARC [redacted]) in July, 2001. Records indicate the recipient had no other hepatitis associate risks factors aside from this transfusion. The recipient presented with signs and symptoms of hepatitis B on October 31, 2001(within the incubation range of hepatitis B, which is 30-180 days). The recipient subsequently expired on November 19, 2001. ARC determined that the two donors were not implicated based solely on the absence of an existing entry in the DDR (Donor Deferral Registry) for hepatitis related reasons and the absence of an existing abnormal hepatitis test result.

a) ARC's determination was based on a review of electronically transmitted interpretations of viral marker tests only. ARC performed no review of actual test records or quality control records associated with hepatitis testing for the two units, to ensure the validity of the test results.

b) ARC's determination was based on a review of the DDR, which found no existing entry for either donor. Furthermore, records contain no documentation of re-contact of the donors for the purpose of retesting or verification of health history.

c) ARC did not trace other products manufactured from units [redacted] and [redacted] to determine disposition or to perform recipient follow-up.

d) On 12/13/02, ARC requested copies of confirmatory test results for the recipient from hospital, the health care facility treating the recipient at the time of death. On that same day, ARC informed hospital that ARC needed to receive the confirmatory test results before further investigation was performed. On 12/14/01, the health care facility provided to ARC copies of test results confirming the presence of recent hepatitis B infection in the recipient prior to death. Records indicate ARC did no further donor testing or donor follow-up. However, ARC informed hospital that ARC's investigation found "each donor denied a prior history of hepatitis or recent exposure to hepatitis at the time of donation" and that the donors "were found to be non-reactive/normal for all hepatitis related tests".

8. The ARC does not perform a thorough investigation of suspected post transfusion hepatitis (SPTHEP) cases as required in Section III.B.14.a of the May 12, 1993 Consent Decree. ARC's current procedure described in BSD 43.103M, Post Donation Information, for the investigation of these cases is limited to an investigation of only those cases involving the transfusion of components from ten or fewer donors. As such, a total of 134 SPTHEP cases across all 36 regions for the period 1/1/00 through 6/30/02, were not investigated because the cases involve more than 10 donors.

9. BHQ only allows the regions to investigate a case that exceeds the ARC's pre-established limit of ten units for litigation reasons or when contacted by a local health department. The regions are required to submit a variance request to

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BHQ when this occurs. For example: in January 2001, the Northern Ohio Region requested such a variance (V-00-275) to perform an investigation in which a recipient who was "confirmed positive" for HBsAg on 10/19/00, was transfused with 36 blood products from 7/99 through 9/00. Variance #V-00-275 was approved with a comment by BHQ that the Northern Ohio region only had to investigate the "8 components relevant to the diagnosis of acute hepatitis." The region's investigation found an implicated donor who was involved in a previous SPTHEP case. The donor was placed in a permanent deferral category [redacted]" This donor would NOT have been located and properly deferred had the region not requested a variance to investigate this case which originally involved 36 blood products due to the ARC's limit of 10 donors.

LOST PRODUCT/TRANSFUSABLE:

10. BHQ has failed to maintain an adequate inventory and distribution system by which the distribution of transfusable blood products can be readily determined to facilitate recall, if necessary. We requested a query of the number of lost products identified in the National Biomedical Computer System (NBCS), since implementation began in 8/96. That query revealed approximately 2620 lost blood products for the period 8/12/96 through 8/12/02. Since the previous inspection in April 2000, the disposition of approximately 1062 blood products can not be determined. This includes the failure of ARC to know the disposition of the following six unsuitable blood products between 1/1/01 through 3/2002, which have positive or no infectious disease test results associated with them.

Region	Date Discovered Missing	Type of Blood Product	Reason for Unsuitability
River Valley	2/9/01	Platelet	Positive for HIV
Appalachian	3/5/01	RBC	HTLV1 RR
Northern Ohio	4/24/01	Therapeutic Whole Blood	No test results
Lewis and Clark	7/9/01	Plasma	HCV Confirmed Positive
Carolinas	3/12/02	Frozen RBC	Missing HIV p24 antigen test results
Southwest	3/12/02	Whole Blood	Repeat Reactive HCV test results

11. BHQ does not monitor the corrective action plan implemented by the regions when unsuitable products can not be located, yet BHQ monitors the corrective action plans when the regions exceed the ARC's established upper control limit (UCL), formerly known as the acceptable quality limit (AQL).

12. There are no written procedures that address BHQ's review of corrective action plans submitted by the regions when a region exceeds the established UCL.

13. The BSLs issued by BHQ that establish an UCL for the regions do not require the regions to investigate or take action to prevent recurrence of lost products unless their individual monthly rate is equal to or greater than the established UCL, or when a region has an upward trend for three consecutive months.

mr 3/20/02

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LOST PRODUCT/PLASMA:

BHQ has failed to maintain an adequate inventory and distribution system by which the distribution of each plasma unit can be readily determined to facilitate recall, if necessary. Several regions have reported the inability to identify the final disposition of plasma products when ARC's Plasma Operations has partially or completely diverted the shipment to another consignee.

14. In [redacted] Case #73173, dated 11/10/98, a region requested information on a database change so that their distribution records would accurately reflect the disposition when BHQ had diverted a shipment the region had made to another consignee. It was determined by BHQ that a special installation procedures, known as a SIP, was necessary to correct the record. On 6/30/00 [redacted] Case #220953), it was determined that a second SIP was necessary to correct the distribution records for plasma products in a partially diverted shipment. [redacted] Case #73173 was closed 7/13/01 with the development of SIP [redacted] and [redacted] Case #220953 was closed on 7/3/01 with the development of SIP [redacted] however, a corrective action was not implemented for 2½ years after the problem was identified.

15. In [redacted] Case #268866 (11/21/00) [redacted] Case #304800 (3/12/01), [redacted] Case #325220 (5/9/01) and [redacted] Case #346749 (7/13/01), various regions reported problems with the length of time the plasma units remain in a "not found" status. All of these cases were closed without correcting the problem.

16. It was not until 1/15/02 when a region submitted a potential system problem that BHQ assigned system problem (SP) #625 and prepared a corrective action plan. The region reported that it was "not uncommon now for cases to be open for 12-24 months and the number of components the region did not have a final disposition for was "currently at about 70 components/month for NBCS."

17. The corrective action plan for SP 625 included a root cause and it was determined that the plasma recall group cannot process recalls in a timely manner because there is no electronic system in place to accurately locate units within a shipment. The corrective action plan indicates one of the corrective actions would be to implement a new software system by the third quarter in 2002 to track recalls on Recovered Plasma units and to manage the Recovered Plasma inventory at the plasma warehouse. On 9/23/02, the corrective action plan was amended to indicate that upon further evaluation the inclusion of the software system was unnecessary and the system problem was closed. There is no record of this evaluation or explanation of how the manual procedures put in place would correct the problem identified in the root cause analysis indicating a need for an electronic system.

18. The effectiveness check for SP 625 indicates an investigation will be initiated if the average response time from fractionators for "found" units is greater than 150 days and the number of "not found" units is not greater than 800 units. These criteria do not ensure that effective recalls can be performed.

19. The plasma disposition notification form for the Greater Chesapeake and Potomac Region, dated 9/5/02, indicates there are at least 52 out of 162 units of plasma that could not be found for recall/market withdrawal.

REISSUE OF UNSUITABLE BLOOD PRODUCTS:

20. The procedures in place to quarantine unsuitable blood products returned to ARC facilities is not always

effective and does not prevent unsuitable products returned, recalled or withdrawn from being reissued. This problem was cited on the FDA-483 during the February –April 2000 inspection of BHQ. During the current inspection, a query was requested of all unsuitable products that had been reissued since the previous inspection. The information provided by the BHQ revealed the following 16 unsuitable products were recalled, market withdrawn or returned to a region and reissued when they should have been discarded.

ARC Facility	***Reason for Product Return, Recall or Market Withdrawal***
Central Plains	On 11/10/2000, donor provided post donation information to ARC; market withdrawal initiated for red blood cell product; product returned to ARC on 11/13/2000; product was reissued on 11/14/2000 but should have been discarded.
Northern California	On 11/28/2000, a hospital returned a red blood cell product to ARC due to excessive air in product bag; product was placed in quarantine; ARC employee expressed the air in an open system but failed to change the expiration date to 24-hours; product reissued (date unknown) prior to supervisory approval
Great Lakes	A leukoreduced red blood cell did not meet manufacturing requirements and was retrieved from the regional subcenter distribution site on 2/2/2001 for destruction; product was reissued (date unknown) to hospital consignee; product returned again for destruction on 2/14/2001.
Greater Alleghenies	On 5/2/2001, Red Blood Cell product was market withdrawn due to post donation information reported by donor regarding a sinus infection; product returned to ARC on 5/3/2001; product was reissued on 5/3/2001.
Badger-Hawkeye	On 5/8/2001, region failed to detect the alteration of the whole blood numbers made by a consignee when two apheresis platelet products were returned to region; these products were reissued to another consignee on 5/8/2001 who reported the improper alterations of the whole blood numbers.
Southwest	Four plateletpheresis products were received outside the temperature requirements; two of the products were reissued before supervisory approval to rework the product labeling; one product was destroyed by consignee on 9/11/2001 yet the consignee of the other product was not notified until 10/4/01 of the recall (disposition unknown)
Tennessee Valley	On 10/18/2001, the region failed to gain control of eight red blood cell products that were manufactured greater than eight hours from time of collection; these products were reissued prior to supervisor approval and before the 11/16/2001 Material Review Board decision.
Heart of America	On 10/30/01, three directed red blood cell products were returned to the region; staff failed to record the temperature of the product upon receipt; supervisor physically placed products in quarantine but failed to place an electronic hold on the products; products were reissued.
Badger-Hawkeye	On 1/11/02, two units were returned to the region with temperature monitoring stickers on them that are not used by the region; regional staff did not notice them during visual inspection and reissued the products on

	1/11/02 and 1/18/02; it was noted by the consignee that the temperature reading on the temperature monitoring stickers were out of acceptable temperature range.
Great Lakes	On 4/10/2002, region received three plateletpheresis units from another ARC region; products had been in transit greater than 24 hours, which exceeded the validated shipping time of the container; region failed to quarantine; one of the products had been reissued and transfused.
Alabama	On 4/25/2002, regional QC on leukocyte reduced red blood cell product failed product quality control; region failed to quarantine and discard per BSD; product was reissued on 5/2/02 and transfused on 5/15/02.
Southern	On 5/6/2002, red blood cell product was reissued and transfused 5/7/2002 after being recalled from another consignee because it was determined that donor had been taking Propecia and should have been discarded.
River Valley	On 7/16/02, donor reported that she had a breast biopsy and results were pending; red blood cell product was market withdrawn on 7/16/02 and placed in quarantine; the medical evaluation instructions dated 7/21/02 were to discard the product; product was reissued on 7/23/2002 and transfused on 7/24/02.
Southern California	On 8/22/2002, a unit of leukoreduced red blood cells was returned by consignee as a possible blood typing discrepancy; product was reissued to another consignee without resolving the blood typing discrepancy; this consignee returned the product on 9/11/2002 due to an ABO discrepancy.
Greater Chesapeake and Potomac	On 4/8/2002, a red blood cell component was returned by a consignee because it was found to be positive for sickle cell and should have been discarded; supervisory had made an incorrect decision and product was reissued on 4/15/2002

RELEASE OF UNSUITABLE PRODUCTS:

A system problem #618 was opened January 2002 when review of data (deviations and Blood Product Deviation Reports) at BHQ revealed regions were releasing unsuitable products when the region failed to quarantine unsuitable products identified through post donation information, products being reviewed by the regional Material Review Boards (MRBs), products identified through review of blood donation records, or products identified through QC records.

21. The data we reviewed indicated that since January 2001 there have been 30 recall events and a total of 1850 components recalled due to collection QC problems. The corrective action included drafting a BSL to change the requirement of the BSD. A supervisor's review of the QC records for collection must take place before using the equipment and supplies for donor screening and blood collection and this review would be added to the batch release checklist. As of June 2002, this BSL had not been released despite the fact that there have been 1850 unsuitable product released that required recall. The SP did not include an effectiveness check to measure effectiveness of the corrective action once implemented.

22. The corrective action plan required for system problem #618 was to issue a field communication for management of post donation information (PDI). Two job aids have been developed but as of June 2002 they have not been released. The job aids restate that the procedures are required by the BSD but does not provide any more

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mechanisms to ensure that the BSD will be followed. The SP that was approved by QA indicates this corrective action will be considered effective if the number of blood product deviation reports (BPDRs) related to PDI is decreased by at least 50%. This is an unacceptable practice for QA to expect anything less than 100% reduction in errors that result in the release of unsuitable products.

23. The corrective action plan indicates that BSL 02-009 was issued on 1/29/2002 on management of products and donors when blood donation record information is missing or discrepant. The system problem, which was approved by QA, indicates this corrective action will be considered effective if the number of BPDRs related to BDRs is decreased by at least 50%. This is an unacceptable practice for QA to expect anything less than 100% reduction in errors that result in the release of unsuitable products.

24. Our review of deviations from 1/1/02 to 6/17/02 during this inspection revealed failure to follow procedures for properly quarantining unsuitable products identified through the MRB in at least 17 deviations and at least 35 deviations when products were not properly quarantined when post donation information was received or BDRs were incomplete. During this time period, 22 BPDRs were logged covering unsuitable products released due to these errors.

INVENTORY MANAGEMENT:

25. BHQ does not provide adequate oversight of inventory management deviations occurring in the regions. BHQ has only performed an assessment of deviations associated with inventory reconciliation of the quarantine locations. BHQ's assessment included a review of regional deviations discovered between 7/27/01 through 6/3/02, during the current inspection. A copy of the only assessment provided during the inspection does not include a date on which the assessment was performed nor any documentation of follow up with the regions, even though BHQ's assessment of the regional deviations identified 234 occurrences in which inventory reconciliation was not performed on all the quarantine locations on a daily basis as required in BSD 78.101M, Component Reconciliation, Version 1.3, implemented 5/18/01.

26. BHQ does not have an adequate inventory management procedure in place to ensure that the disposition of blood products can be readily determined. In addition, BHQ has failed to determine the reasons the regions are continuing to ship components physically but not recording them electronically in NBCS. During the inspection, we requested a query of deviations associated with extra or missing units in a shipment for the period 7/1/2001 through 6/30/2002, which may have resulted in a discrepancy between the physical and electronic locations of a blood product and may result in lost products. A total of 233 deviations occurred during that period. An assessment has not been performed by BHQ nor has there been any follow up with the regions. .

27. We requested a query of inventory reconciliation problems for the period 7/1/00 through 6/30/02. The query revealed approximately 1365 deviations being reported by the regions for various problems with inventory management, many of which were classified as LCT (log, correct, trend) deviations. Some examples include daily inventory reconciliation of quarantine locations were not being performed and blood products could not always be located during inventory reconciliation. These types of deviations are not investigated for root cause analysis and corrective, per BSD 92.103T, Deviations, version 1.1, April 2001. Inventory reconciliation deviations are occurring even after a team of representatives from BHQ and the regions, known as the Inventory Management Quality Team (IMQT), reviewed the inventory processes and presented their final recommendations for improving inventory management in the fall of 2000 to management with additional evaluations made in March 2001 and March 2002.

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FROZEN RED BLOOD CELL INVENTORY:

BHQ has failed to provide adequate procedures for inventory and release of frozen Red Blood Cells. In April 2001, a BHQ audit of the Gulf Coast region identified three problems with the storage and quarantine of frozen Red Blood Cells. The problems included the failure to place an autologous frozen Red Blood Cell with an [redacted]" assertion/deferral in physical quarantine, three rare frozen Red Blood Cells that had not been tested for HIV antigen were not on the quarantine report; and there was no electronic quarantine location in NBCS for rare frozen Red Blood Cells.

28. The region responded to the audit findings indicating that when the [redacted]" assertion was added there was no requirement to perform a lookback and place the unit in quarantine. However, it was not until this inspection, over one year later, that this problem was investigated. According to BHQ, they determined this to be a performance problem as the regions had been required to perform lookback. In response to the other two BHQ audit observations, the region responded that the National Reference director was currently writing a BSL to handle rare frozen RBC. The region submitted a SP indicating there was no electronic inventory location for rare frozen Red Blood Cells. BHQ had informed the region that the electronic inventory location would be in NBCS [redacted] in June 2001. The electronic inventory location has still not been implemented and the BSL was not issued until this inspection on May 31, 2002.

29. System Problem #580 was submitted to BHQ by the region on 5/10/01. The failure to have an ability to electronically quarantine the rare frozen RBC was determined not to be a system problem because it was similar to a commitment to FDA #00.972, and would be included in that process and a BSL was in process to address the issue. The FDA commitment logged as #QA/RA log #00-972 was based on an FDA observation in the Southern Region in October 2000 which indicated that there were no written procedures for management of non-NBCS product. This is not the same problem as the failure to have an electronic inventory location for NBCS product and as of the June 2002 the corrective action for QARA log #00-972 indicated BHQ was performing an evaluation of rare frozen units and would provide the regions with directions for handling these units in the very near future.

30. During the conversion to NBCS in 1997, the regions were informed that they would be provided instructions on handling frozen Red Blood Cells that could not be loaded into the NBCS system after implementation. This was never done. When the BSL 02-109 was finally released on 5/31/2002, procedures were still not provided. The regions were informed in the BSL they were to manage labeling and the release of any frozen RBC with regionally developed procedures. BHQ will release a standard process in the future, "if required."

CMV LABELING:

BHQ has failed to take adequate corrective action to ensure blood components are properly labeled for cytomegalovirus test results (CMV). During the previous FDA inspection (February/April 2000) of BHQ, FDA identified errors dating back to 1998 with the erroneous release of CMV positive blood products, or blood products not tested for CMV, labeled as CMV negative. ARC promised corrective action following that inspection, but these errors continue.

31. ARC began a manual verification of CMV labeled components following the February-April 2000 FDA inspection until a computer enhancement was delivered to all regions in December 2000. In January 2001, two regions [redacted] case #284457 and #286576) reported that the potential for "erroneous release due to improper CMV labeling still exists" despite the computer enhancement in NBCS [redacted]. Both [redacted] cases were closed by BHQ, which referred to

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 -- 12/20/02
6000 Metro Drive, Suite 101 Baltimore, Maryland 21215	FEI NUMBER: 1000123507
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Ramesh Thadani, Executive Vice President and Chief Executive Officer	
FIRM NAME American National Red Cross/Biomedical Services	STREET ADDRESS 1616 Fort Myer Drive
CITY, STATE AND ZIP CODE Arlington, Virginia 22209	TYPE OF ESTABLISHMENT INSPECTED National Headquarters of a Licensed Blood Bank

another proposed computer enhancement identified as [redacted] In March 2001, another region reported an erroneously released component (deviation #2001-027-000635) labeled as CMV negative although the components actually tested CMV positive. The deviation report noted that the component was labeled using NBCS version [redacted] and the region attributed the error to "the failure of computer system to require electronic verification of the whole blood number." Despite this reports from at least three regions that the process change had not adequately corrected the CMV labeling problem, BHQ took no additional corrective action.

32. In March 2001, BSL 01-043 only required the manual verification for a period of four months in order to determine the effectiveness of the software change related to CMV labeling delivered in NBCS version [redacted] This BSL was issued despite the fact the regions had already identified the computer change as ineffective. From April to July 2001 twenty nine deviations involving release of components mislabeled with CMV test results were identified by the Regions. There is no record of an assessment of these deviations by BHQ to determine the cause of the deviations, and no corrective action was taken.

33. In July 2001 BSL 01-147 was issued indicating "based on data that has been submitted" the manual verification of the CMV labeling would continue until further notice. There is no record of what data was submitted and reviewed or the results of the review. Again, there was no change to the labeling procedure. From August 2001 to June 2002, 59 CMV deviations were identified by the regions. The only corrective action taken was to issue a BSL 02-110 (CWU #454) dated June 4, 2002, instructing regions to review the CMV labeling procedure and toverify with staff.

34. During the current inspection, our review of approximately 49 deviation reports revealed that in approximately 22 cases the CMV labeling error was discovered at distribution. This indicates that the products were improperly labeled and the errors were not identified during the manual verification step (effectiveness check) required by BSLs 01-043 and 01-147. In approximately 22 cases, the region logged the errors as events or log, correct and trend (LCT) deviations and did not determine a root cause or corrective action. There is no evidence that BHQ identified the failure of the regions to investigate the errors or detected that software changes related to CMV labeling, released in NBCS version [redacted], is an effective corrective action. There is no evidence that BHQ recognized that the manual verification failed to detect and correct CMV labeling errors.

35. BSLs 01-043 and 01-147 required regions to report CMV labeling deviations noted during the manual review (effectiveness check) to BHQ. During this inspection, our random review of deviation reports indicated that CMV labeling errors, identified during distribution, shipping, or labeling following irradiation, are not always reported for evaluation. For example: deviation # 2001-006-003266, #2002-018-000240, #2002-053-002029 and #2002-020-001252 were not reported as required by BSL's 01-043 and 01-0147. Deviation reports submitted by the regions also do not indicate that all components in the labeling session (batch) are reexamined once a labeling error is discovered on one of the components in the session to ensure no other components are incorrectly labeled for CMV.

36. On July 25, 2001, a region submitted a potential system problem on the CMV labeling process as a result of an FDA inspectional observation. The problems were determined to meet ARC's criteria for a system problem and System Problem #602 was assigned on 7/30/01. On 1/31/02, the records indicate that progress on the system problem had not been made due to "resource constraints." A CAP (Corrective Action Plan) completed 3/1/02--seven months after the original system problem was submitted-- indicates that two of the three problems noted in the system problem had been corrected, that the third would not be implemented, and that the pilot in several regions would be performed. The system problem was closed on March 12, 2002. The CAP states that the "Tracking and Trending data and CMV effectiveness

check data support that the software modification coupled with the manual verification have been effective in preventing the release of CMV mis-labeled products." However, the software modification referred to was the original corrective action implemented in NBCS version [redacted]. This 3/1/02 CAP was approved by QA. There is no evidence that QA evaluated the labeling errors found during the manual review (effectiveness checks) required by BSLs 01-047 and 01-143. Those errors indicate the CMV labeling process is not properly controlled since the manual review (effectiveness checks) continued to identify errors and since numerous deviations had been identified at distribution/shipping that had not been identified through the manual review (effectiveness check) process. The CAP again addressed the need for a computer enhancement [redacted] which was originally recommended as a corrective action in January 2001 but not yet implemented, over one year later.

37. On 6/12/02, a region reported in Biological Product Deviation Report #2002-011-001692 the erroneous release of three components labeled incorrectly as CMV negative. One of these products was transfused prior to recall. The investigation revealed these three products were among 18 products incorrectly labeled as CMV negative that had been released for distribution. This region had at least nine prior deviations that indicate errors had occurred in the CMV labeling process. All of these deviations were classified by ARC as "LCT," and no root cause analysis or preventative action was taken.

38. On 7/26/02, another region reported in Biological Product Deviation Report #2002-002-001618 the erroneous release of one component labeled incorrectly as CMV negative when the components tested CMV positive. This component had been distributed to a hospital incorrectly labeled and was only identified by the region during reshipping since the product was returned to the region by that hospital during a routine stock rotation.

39. During this inspection, another System Problem #646 was opened following the second occurrence (Deviation #2002-002-001618) of the distribution of a component whose CMV status had been incorrectly labeled. The CAP indicates a new procedure will be distributed to the field requiring CMV negative products to be labeled in a separate labeling session. The CAP also indicates two NBCS enhancements ([redacted] and [redacted]) will be evaluated; however, no commitment to implement these enhancements is included. The CAP for System Problem #646 approved by QA indicates the proposed changes in the CMV labeling process will be considered effective if there is a 63% reduction in deviations. This percent reduction was determined by use of an unwritten and unapproved procedure recommended by the BHQ's accounting department, and has no relationship to the potential health risk to the recipient transfused with a blood product incorrectly labeled as CMV negative.

NATIONAL DONOR DEFERRAL REGISTRY:

BHQ has failed to implement adequate procedures to ensure that the National Donor Deferral Registry (NDDR) contains the names of all permanently deferred donors identified by the regions or that the donor information contained in the NDDR is accurate. For example:

40. [redacted] case #199404 was submitted by the Indiana-Ohio Region on 4/21/00 because two donors were submitted by region to the NDDR several times but were still not appearing in the NDDR. This prompted BHQ to develop two queries to determine whether other donors with [redacted] class assertions (permanent deferral) or [redacted] class assertions (surveillance category) were missing from the NDDR.

a) One query (SIP[redacted]) was developed to identify any donors found in the regional database with an '[redacted]

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
6000 Metro Drive, Suite 101 **Baltimore, Maryland 21215**	FEI NUMBER: 1000123507
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: **Ramesh Thadani, Executive Vice President and Chief Executive Officer**	
FIRM NAME American National Red Cross/Biomedical Services	STREET ADDRESS 1616 Fort Myer Drive
CITY, STATE AND ZIP CODE Arlington, Virginia 22209	TYPE OF ESTABLISHMENT INSPECTED National Headquarters of a Licensed Blood Bank

assertion but not found in the NDDR. SIP [redacted] was initially run on 5/1/00 in all regions and the results revealed 320 donors with [redacted] assertions were identified in the regional donor deferral registry but not included in the NDDR. BHQ failed to determine the frequency in which this SIP should continue to be run to assure that there are no additional donors with an '[redacted]' assertion that are not found in the NDDR. This SIP was not run in 6/2000; 8/2000; 9/2000; 11/2000; 12/2000, and the problem identified [redacted] case #199404 has not been resolved.

b) The other query (SIP [redacted] was developed to identify donors found on the regional database with a '[redacted]' assertion that are not located on the NDDR and classified by BHQ as being "important." It was first run 5/8/2000 on all regions. This SIP identified 3000 donors with '[redacted]' assertions that were not found in the NDDR. BHQ failed to determine the frequency in which this SIP should continue to be run to assure that there are no additional donors with a '[redacted]' assertion that are not in the NDDR. SIP [redacted] was not run in the following months: 6/2000; 7/2000; 8/2000; 9/2000, 11/2000; 12/2000; 2/2001 or 3/2001. SIP [redacted] was modified in June 2001 and renamed SIP [redacted] Again, BHQ did not determine the frequency in which this "important" SIP should be run. The modified SIP #[redacted] was not run 7/2001 or 9/2001, and the problem identified in [redacted] case #199404 has not been resolved. SIP [redacted] was run as recent as 6/02 and four regions reported discrepancies.

41. BHQ initially informed the regions on 6/29/00 in BSL 00-115 entitled "Limitations Between NBCS and the National Deferral Register (NDDR), Follow-up to BSL 00-090 and Enhancements to Procedures," that the NBCS allows punctuation in the donor's record but the NDDR database will reject the records that contain certain punctuation in the donor name field. BSL 00-115, which instructed the regions not to use certain punctuations when entering data, was issued. BHQ failed to determine whether regions were following this BSL to assure that donors were being screened against the local and national DDR.

42. The problem with utilizing punctuation in the donor name field continued. [redacted] case #292837, dated 2/5/01, the Alabama Region reported another BDR problem when a donor's last name contains an apostrophe. On 2/8/01, BHQ issued additional instructions to the regions in BSL 01-024 entitled, "Limitations When Performing a DDR Query to Screen against the Local and National DDR" to the regions to alert them to this "potential hazard." This BSL instructed regions to omit the apostrophe in the donor search fields when performing the DDR query. SIP #[redacted] was then released on 3/6/2001 to all regions to identify any donors with potential matches in the NDDR. The results of the query revealed 39 donors who had not been screen properly screened against the NDDR.

43. On 2/27/2001, it was discovered that BHQ's Biomedical Information Staff failed to manually enter three donor records into the March 2001. Therefore, the NDDR did not contain the correct information until the next cycle in April 2001.

44. In May 2001, BHQ's Biomedical Information Staff failed to perform a comparison of the national copy of the NDDR against each regional copy of the NDDR. This failure was discovered when two regions had found 30 discrepant records during the March 2001 DDR cycle.

45. [redacted] case #390441 was filed on 11/26/01 because three donor files were rejected by the NDDR. BHQ determined the cause to be a software defect that was introduced when NBCS version [redacted] was implemented in the regions. SIP [redacted] was developed to correct a software defect in a previous version of the NBCS but instead introduced a problem when NBCS version [redacted] The problem introduced caused problems with finding matching files on the NDDR; SIP [redacted] was developed to correct the problem but did not; and SIP [redacted] was developed to remove the change made in

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
6000 Metro Drive, Suite 101 Baltimore, Maryland 21215	FEI NUMBER: 1000123507
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Ramesh Thadani, Executive Vice President and Chief Executive Officer	
FIRM NAME American National Red Cross/Biomedical Services	STREET ADDRESS 1616 Fort Myer Drive
CITY, STATE AND ZIP CODE Arlington, Virginia 22209	TYPE OF ESTABLISHMENT INSPECTED National Headquarters of a Licensed Blood Bank

SIPs [redacted] and [redacted] so that the spacing in the software was properly preserve to prevent this software problem from occurring. On 12/20/01, SIP [redacted] was run to assure that all donors were properly deferred. This query did identify numerous donors but, fortunately had already been deferred for a health history reason, tested positive on a current donation, or had an assertion applied which prevented distribution of products.

46. A retrospective review by the Southern California Region revealed that of the 4012 HBsAg confirmed positive donors who were identified during the review dates of 1979 through 1987, 243 of those were missing from the NDDR. One donor was found to have made subsequent donations which had to be recalled in April 2001.

47. BHQ has allowed a workaround to be in place since 7/13/94 for a software problem in the NDDR system. This problem occurs when a manual change is made to a donor record that affects the soundex value (date of birth or last name) but the change fails because the NDDR rejects the donor record. BHQ did not submit an NDDR software change request until 4/23/01 and did not make the software change until 1/15/02 in NDDR version [redacted], nearly eight years later.

DONOR FILE CHECK:

Regional facilities use the Donor File Check process when they discover that a donor was not properly entered into the National Donor Deferral Register (NDDR). Each region is required to submit the names of those donors not entered into the NDDR to BHQ. BHQ is then required to compile a comprehensive list of deferred donors not placed on the NDDR and distribute the list to all regions with a BSL instructing the regions to verify if any donor on the list has donated during a specified time period. The regions must then perform recalls or market withdrawals of any distributed blood or blood products collected from any of the donors within the specified time period. FDA found that Donor File Check procedures were inadequate and were not being followed in the previous FDA inspection in February-April 2000.

48. BSD 43.101M, Donor Deferral Register, is inadequate because it does not include the complete Donor File Check process required to be performed by the regions. It does not include the process the regions currently perform when they receive the consolidated list of donors from BHQ and determine whether the donor had donated in other regions and whether products had been released. Currently, this process is described in a monthly BSL issued to the regions by BHQ.

49. There is no formal training for regional personnel performing the donor file check investigations. Therefore, BHQ cannot assure that the donor file check process is being performed accurately by the regions and that unsuitable products have not been released. The monthly BSLs issued by BHQ state that "no training" is required and, because BSD 43.101M does not include the complete donor file check process, regional personnel are not formally trained during BSD 43.101M training.

50. BHQ did not provide proper guidance to the regions on how to initiate a search as instructed in the monthly BSLs to the regions, until FDA addressed this during the inspection of the Greater Chesapeake and Potomac Region. BHQ added an explanation of "search" in BSL 02-128, Donor File Check, dated 6/28/2002, but has not included it in BSD 43.101M.

51. BHQ failed to follow LOP 10.515, Donor File Check Procedures, Effective Date 1/6/00, which requires monthly distribution of the Donor File Check list to all regions. Donor File Checks were not performed for the following months: June 2000, July 2000, September 2000, October 2000, November 2000, and January 2001.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
6000 Metro Drive, Suite 101 Baltimore, Maryland 21215	FEI NUMBER: 1000123507
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Ramesh Thadani, Executive Vice President and Chief Executive Officer	
FIRM NAME American National Red Cross/Biomedical Services	STREET ADDRESS 1616 Fort Myer Drive
CITY, STATE AND ZIP CODE Arlington, Virginia 22209	TYPE OF ESTABLISHMENT INSPECTED National Headquarters of a Licensed Blood Bank

52. BHQ does not review the regional deviations associated with the donor file check to assess the reasons ineligible donors were not placed into the NDDR at the time the donor was found to be in either an [redacted]' or [redacted] category. BHQ has not performed an assessment to determine whether a system problem exists with the donor file check process.

53. BHQ allows the regions to take up to one year to research whether the donors on the BHQ consolidated donor file check list donated in their regions. One example was when BHQ issued BSL 00-288 to all regions on 12/7/00. BHQ gave the regions a due date of 2/8/02 to complete research on the donors listed on List III and IV, which are attachments to BSL 00-288. Note: List III contained donors submitted from various regions who qualified for the NDDR prior to 1990; and List IV contained donors submitted from various regions who were involved in the RCTA (regional confirmatory testing audit) and who qualified for the NDDR prior to 1990. Research performed by the regions and reported to BHQ revealed that donors who should have been in the NDDR did donate in other regions and products had to be recalled. For example:

Region	***Donors who should have been listed in the NDDR but had donated in other regions***	***# of products released from this donor and recalled***
New York-Penn	1	2
North Central	1	5
North California	1	3

54. BHQ has exempted donors placed in certain Category/Subcategory [redacted] from having to be included in a monthly donor file check. Category/Subcategory [redacted] is the category for donors who are permanently deferred. All regional Category/Subcategory [redacted] donors must be entered into the NDDR as required in BSD 43.104M, Donor Deferral Management. BHQ issued this Category/Subcategory [redacted] limitation in BSL 02-061, Policies for Donor File Checks, on 3/28/02. This change was approved and signed off by the Vice President QA/RA on 3/22/01 and implemented on 3/28/02. This change will result in failing to identify unsuitable products that have been released and are, therefore, subject to recall. Category/Subcategory [redacted] donors who are not included in the donor file check process include donors at high risk for HIV, hepatitis, and CJD and are as follows:

Category [redacted]: Donors who have used illegal drugs, have a history of positive screening for HIV, who have signs/symptoms of AIDS, males who have had sex with another male, who have been treated with clotting factor concentrates for a bleeding disorder such as hemophilia, and who have provided sex for drugs or money.

Category [redacted]: Donors who were born, lived and/or received blood transfusion or medical treatment with a blood product while in Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria; or had sex with anyone born in or lived in the above mentioned countries.

Category [redacted]: Donor sample was indeterminate using a licensed HIV-1 Wb test and EIA nonreactive for anti-HIV-2.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
6000 Metro Drive, Suite 101 Baltimore, Maryland 21215	FEI NUMBER: 1000123507
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Ramesh Thadani, Executive Vice President and Chief Executive Officer	
FIRM NAME American National Red Cross/Biomedical Services	STREET ADDRESS 1616 Fort Myer Drive
CITY, STATE AND ZIP CODE Arlington, Virginia 22209	TYPE OF ESTABLISHMENT INSPECTED National Headquarters of a Licensed Blood Bank

Category [redacted] Donor sample was anti-HIV-1/HIV-2 repeat reactive and sample collected at least six months later was anti-HIV-1/HIV-2 repeat reactive, negative on a licensed HIV-1 Wb (confirmatory test), and EIA nonreactive for anti-HIV-2.

Category [redacted] Donor uses the call-back procedure to exclude his or her donation, but does not provide any other information.

Category [redacted] Donors involved in two SPTHEPs or a donor is the only source in a SPTHEP.

Category [redacted] Donor deferral based on results of research studies.

Category [redacted] Since 1/1/80, an individual has spent a total time that adds up to three months or more in the United Kingdom or six months in any combination of countries listed in the BSD. Also, an individual who has had a blood transfusion in any of the countries listed in the BSD.

Category [redacted] Two consecutive donor samples collected at least eight weeks apart are both repeat reactive, and not confirmed positive for HBsAg; donor has passed the FDA HBsAg reentry protocol two or more times followed by unconfirmed repeat reactive HBsAg and anti-HBc nonreactive test results.

AUTOASSERTION [redacted] SYPHILIS:

During the previous FDA inspection in February-April 2000, we found problems with the auto assertion of deferral code [redacted] (syphilis deferral). BHQ handled the problem as a potential hazard. BHQ developed a workaround on 1/6/99 and a query (SIP [redacted]) to identify the incorrect records. A software fix was released in NBCS vs. [redacted] on 9/28/99.

55. Following the software "fix" and correction to any incorrect records, SIP [redacted] was run in all regions on 11/16/99 ([redacted] 15603 and 155498). There are no records of review.

56. Reportedly, SIP [redacted] was run again on 9/28/00 as an effectiveness check. A note in [redacted] case #249993 indicates all records were correct except for the South Carolina Region. There are no records of this review other than the note in the [redacted] case.

57. Deviation 2000-036-004636 from the South Carolina Region indicates four of the five whole blood numbers listed on SIP [redacted] were collected after the workaround was in place. BHQ conducted no investigation into why the workaround was not followed or why the five whole blood numbers were not identified in the previous SIP [redacted] on 11/16/99 and corrected.

58. On 1/31/02, SIP [redacted] was run on a few regions as a "spot check." It was determined at this time that the Carolina Region had 11 donations without the correct assertion and that five components from two subsequent donations had been released and were recalled.

59. A review of SIP [redacted] run on 9/28/00 was not completed and documented until 2/7/02.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
6000 Metro Drive, Suite 101 Baltimore, Maryland 21215	FEI NUMBER: 1000123507
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Ramesh Thadani, Executive Vice President and Chief Executive Officer	
FIRM NAME American National Red Cross/Biomedical Services	STREET ADDRESS 1616 Fort Myer Drive
CITY, STATE AND ZIP CODE Arlington, Virginia 22209	TYPE OF ESTABLISHMENT INSPECTED National Headquarters of a Licensed Blood Bank

60. BHQ failed to implement an effectiveness check to ensure regions were properly following the workaround. There were no BHQ deviations written for the failure to review and document SIP results. There was no record showing exactly how many times the SIP was run until a list was created during the inspection at FDA's request.

DONOR HOLD:

BHQ failed to perform a timely and thorough investigation into the root cause of the problem occurring when a computer hold is placed on a donor while discrepancies with the donor information are being resolved during the registration data entry process. If the computer hold is released before making corrections to these discrepancies, the donor's new information is not screened against the local and national donor deferral register. This may result in the release of an unsuitable blood product. This problem was initially discovered by the ARC on 7/22/99 and addressed during FDA's previous inspection of BHQ (February-April 2000) because the corrective action implemented at that time was inadequate. During the current inspection, we determined that this problem was not properly addressed until 4/16/02, some four years after ARC initially discovered it. A review of the various corrective actions implemented by BHQ for this problem between 6/15/00 through 4/16/02 revealed that BHQ did not implement an adequate corrective action. For example:

61. BHQ's investigation into the problem and the various corrective actions implemented between 6/15/00 through 4/16/02 did not address why the regional users were not following the procedures and whether the established employee training was adequate to prevent this problem from recurring.

62. BHQ implemented BSL 00-126 entitled "Follow Up Actions Required for Releasing Donor Identification Holds" on 6/15/2000 as part of the corrective action. This BSL was not being followed by the regions as the FDA found during inspections of the Mid Atlantic Region and the Appalachian Region in February/March 2001 and January 2001, respectively, the problem with releasing the donor from hold before making changes was continuing. BHQ's investigation did not include a review of the adequacy of employee training and the instructions for training in this BSL stated "No training is required for this BSL."

63. On 3/13/01, BHQ implemented BSL 01-044 entitled "Update #2: Follow-Up Actions Required for Releasing Donor Identification Holds" to provide additional information on releasing donor identification holds and instructions for performing the monthly reviews. However, this BSL was found to be inadequate on 3/15/01 and 3/16/01 by the Gulf Coast Region and the New York Penn Region, respectively, due to discrepancies in the associated Training Implementation Plan. BHQ did not issue a corrected procedure until the issuance of BSL 01-064, entitled "Update #3: Changes to Donor Registration and Supervisory Review and Releasing Donor Identification Holds" on 4/12/01, nearly four weeks later.

64. BSL 01-064 required all regions to review the results of a query (SIP [redacted]) to determine whether they were releasing donor identification holds in the proper sequence. A review of reports submitted by the regions for the month of June 2001 revealed ongoing problems in which changes to donor information were being made after the release from hold in approximately 30 donations. BHQ's investigation was inadequate as it did not address the reason why the regional users were not complying with the procedures issued by BHQ and whether the training plan was adequate.

65. BHQ issued BSL 01-151 entitled "Final Record Review of the Releasing Donor Identification Hold Query" on 7/26/01 which made BSL 01-064 obsolete. A review of the final information submitted by the regions revealed continuing problems with changes to donor information being made after the release from hold in approximately 26

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Marcia Corbin, Investigator Linda S. Mattingly, Investigator Stephany J. Wesley, Investigator	12/20/02

donations. Again, BHQ's investigation was inadequate as it did not address why the regional users were not complying with the procedures issued by BHQ or whether the training plan was adequate. Again, the BSL did not require any employee training.

66. A software change was made to correct the donor hold sequence in NBCS version [redacted] that included the [redacted] Report functionality that would ensure information changed on the donor would be automatically screened against the NDDR. This version release was implemented in all the regions between 7/9-31/01. Then NBCS version [redacted] was implemented beginning on 10/27/01 and, on 11/14/02, while attempting to correct a software problem in version [redacted] a new problem was introduced which affected the [redacted] Report functionality. This, consequently, caused the [redacted] Report to erroneously issue a message "No potential matches found" when users were expecting the report to flag any donor(s) that may be a potential match against information in the NDDR. This erroneous message created the potential for the erroneous release of unsuitable blood products. BHQ did not notify the regional users of the software defect until 12/11/01 when BSL 01-275 was implemented to instruct the regional users to manually check the NDDR when changes are made to donor identifying information before releasing the hold.

67. BHQ had to install a software fix to address the problem that was occurring when the NDDR hits were not appearing on the [redacted] queries. BHQ reloaded the DDR after applying SIP [redacted] to assure all donor deferral information was loaded into the DDR table properly. This was completed in all regions by 12/28/01 except in the Badger Hawkeye Region which implemented it on 1/2/02. BHQ was required to file an FDA Medwatch Report on 1/8/02 due to the severity of this problem and because the possibility an erroneous release of unsuitable products may have existed due to this software problem in NBCS.

68. BHQ then developed a query (SIP [redacted]) to determine whether any donor records had a change in their last name, SSN, or DOB, did not have an [redacted] class assertion, and was a hit with someone on the NDDR using their current record or before image record. The regional users were then required to review the results of the query and determine whether the erroneous release of products occurred. This query was initially run from 11/11/02 through 12/20/01, and again from 12/20/01 through 1/2/02. The information produced from SIP [redacted] and reviewed by the regional users was not assessed by BHQ until 4/16/02 when BSL 02-078 entitled "Discontinue the manual DDR Query when Changes are made to Donor Identifying Information" was implemented in all regions.

69. On 12/19/01, a QA audit determined that one region had 508 records on registration hold because information on the blood donation record was discovered either to be missing or discrepant with the information currently in NBCS for the donors. BSD 43.301M requires that all registration holds be resolved in 48 hours, yet these 508 unresolved records had been placed on hold between July 2001 and December 2001. There was no record provided documenting the BHQ investigation into this problem, including no record to show whether BHQ determined if other regions were following the BSD for resolving registration holds within 48 hours. There was no investigation into the failure of QA to identify the problem of 508 unresolved records for at least six months.

70. A BSL 02-084 was issued on April 25, 2002, which reminded regions to resolve donor identification holds within 48 hours. The BSL also states that some of the holds were in existence prior to the BSD being put in place; however, there is no record of the investigation that made this determination.

71. The change control forms used to track the BSL 02-084 development indicate that an effectiveness check would be performed and a report would be run to ensure all discrepancies/holds greater than 48 hours had been identified.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
6000 Metro Drive, Suite 101 Baltimore, Maryland 21215	FEI NUMBER: 1000123507
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Ramesh Thadani, Executive Vice President and Chief Executive Officer	
FIRM NAME American National Red Cross/Biomedical Services	STREET ADDRESS 1616 Fort Myer Drive
CITY, STATE AND ZIP CODE Arlington, Virginia 22209	TYPE OF ESTABLISHMENT INSPECTED National Headquarters of a Licensed Blood Bank

This was approved by BHQ on 2/14/02. On 3/27/02, the change control form indicates the effectiveness check was eliminated by BHQ since QA staff and regional supervisory staff would be reviewing the records. However, it was the QA staff and the regional supervisory staff in the region who had failed to identify this problem.

PICK PAN:

During donor registration, a list of potential donors is displayed on the computer screen which ARC refers to as the "pick pan." During the previous inspection in February – April 2000, problems were noted with operators selecting the wrong donor from the "pick pan" resulting in the donation becoming associated with a wrong donor in the database.

72. The corrective action implemented by BHQ to prevent data entry personnel from selecting the incorrect donor during donor registration is not always effective even after BHQ implemented in June 2000 a supervisory review of the donor's registration computer record against the BSD and an enhancement in January 2001 when NBCS version [redacted] was released so that it would now automatically populate the fields when the last name, social security number, date of birth, and sex match exactly. BHQ issued BSL 01-165, Monthly Donor Registration Data Entry and Record Review Effectiveness Check, August 10, 2001, to monitor on a monthly basis the number of times a discrepancy occurred between the BDR and whether any incorrect records were selected from the pick pan. BHQ terminated their monthly assessment in April 2002, even though the regional monthly reports revealed there were still instances of the incorrect donor information was being selected from the "pick pan."

73. BHQ has not reviewed retroactively donor files in NBCS to determine whether donors were properly evaluated and selected from the pick pan during donor registration.

DUPLICATE DONOR RECORDS:

74. BHQ performed a retrospective review of records on 4/15/02 and noted that the Puerto Rico Region had reported to BHQ on 11/16/00 the failure to correct duplicate records as required. The report was never forwarded to FDA as required in paragraph III.B.9 of the May 12, 1993 Consent Decree of Permanent Injunction. The Southern Region had reported the failure to correct duplicate records as required on 4/30/01 and the report was never forwarded to FDA as required by the Consent Decree. Both reports were forwarded to FDA during this inspection on 5/20/02. A deviation report #2002-090-000123, dated 4/15/02, did not identify the root cause for this problem or any preventative action. On 2/13/02, BHQ reported to FDA the failure to correct duplicate records by the Missouri-Illinois Region. A complete investigation has not been performed to determine if any other region has failed to correct and report duplicate records.

MISSING/INCORRECT INFORMATION ON BLOOD DONATION RECORDS:

BHQ has failed to establish adequate procedures for obtaining the medical history, donor identity and donor vital signs. During the FDA inspection of the Salt Lake City region in March/May 2001, approximately 3500 deviations had been recorded by the region in approximately 11 months for missing, incomplete or inadequate information on the BDRs.

75. BPDR #2002-041-000380 (11/1/01) indicates during an audit in another region 29 records in November 2001 had questions that were not answered and the omissions were not discovered during the regional review process. Forty four components were recalled as a result. The effectiveness check states the corrective action will be proven effective when there is a "significant decrease" in staff not answering questions and units being destroyed.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
6000 Metro Drive, Suite 101 Baltimore, Maryland 21215	FEI NUMBER: 1000123507
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Ramesh Thadani, Executive Vice President and Chief Executive Officer	
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76. A review of Biological Product Deviations (those deviations which are filed with the FDA because unsuitable blood products were released) for the period 12/30/01 through 6/1/02 identified approximately 35 occurrences in which blood products were released. The BDRs associated with these products were not complete and contained missing information, even after undergoing 200% review.

77. A pilot program was approved in two regions on 7/30/2001 to study the effect of performing BDR review prior to blood collection. Following this trial several recommendations were made by ARC staff in 11/14/2001, including modifying collection staffing to assign a staff person to perform BDR review prior to phlebotomy. No corrective action was implemented.

78. On 6/7/2002, the Vice President, QA Blood and Plasma Operations, recommended this pilot be conducted in two additional regions to determine if the recommendations from the trial will have similar effects in other regions. This decision was not made until FDA requested the follow up during this inspection.

ACCEPTANCE OF INELIGIBLE DONORS:

BHQ has failed to implement an effective system-wide corrective action for known critical deviations involving the distribution of unsuitable blood products collected from donors not eligible to donate, including but not limited to donors traveling to a high risk malarial area, taking certain medications, or traveling to specific European countries. A review of Biological Product Deviation Reports (those deviations filed with the FDA because unsuitable blood products were distributed) was performed by FDA for the period 12/20/01–6/1/02.

79. Blood products from approximately 58 donors were found to be collected and distributed even though the donors had reported to the health historian information about traveling to a malarial endemic area. The health historian should not have allowed the donation to occur. In addition, blood products from these donors were distributed even after the donors' BDRs had undergone a 200% review. ARC informed the FDA in a Paragraph VI.B response dated 1/30/02 (Bates Page 025377), related to the inspection of the ARC's Salt Lake City facility in March-May 2002, that "Red Cross has promptly and aggressively taken a series of actions to improve the review and evaluation of the BDR by the health historian for donor travel in a zone requiring deferral for malaria..." Even with the actions taken by the ARC, including revisions to BSD 51.110M and revisions the associated job aide 51.110M/JA07 on 1/15/01, 8/10/01, 10/15/01, and 11/16/01, health historians are not always adequately determining whether a donor has traveled to a malarial endemic area. The "Trainer Guide" for BSD 51.110M, Blood Donor Interview, Processing, and Management, Version: 1.10, November 2001, provides little information to trainers to assist them in providing training to employees responsible for making geographical decision for malaria areas.

80. Blood products from approximately 16 donors were collected and distributed even though the donors had reported to the health historian information about taking certain medications. The health historian should not have allowed these donors to donate. In addition, blood products from these donors were distributed even after the donors' BDRs had undergone a 200% review.

81. Blood products from approximately 48 donors were collected and distributed even though the donors had reported to the health historian various information that should have made them ineligible to donor, such as living in Europe for two years and having a history of hepatitis. The health historian should not have allowed these donors to

donate. In addition, blood products from these donors were distributed even after the donors' BDRs had undergone a 200% review.

RED BLOOD CELL MANUFACTURING:

BHQ has failed to assure that Red Blood Cell components are being manufactured in accordance with the manufacturing instructions and written procedures for leukoreduced products.

82. In July 2001, the North Central Region discovered that Red Blood Cell components were not being manufactured within eight hours of collection when held at room temperature. This problem was first identified by the North Central Region on 7/13/2001 and discovered to have been occurring since 4/20/98, the NBCS implementation date. Consequently, a large recall of approximately 5300 components was performed by the North Central Region. Yet, BHQ did not determine whether this problem was occurring in other regions or corrective action until BSL 01-223, Failure to Prepare Red Cell Components within Timing Guideline was issued to the regions on 10/10/01. This BSL required regions to review their current workflow, operational process controls to determine whether they are following the manufacturer's package insert, BSD 62.200M and BSD 62.201M.

83. Other regions were found to be having difficulty following the procedures. For example: In 10/26/2001,Great Lakes recalled approximately 75 indated red cells that missed the eight hour time frame, but the region did not recall outdated red cells based on the following rationale: "The region had procedures in place to protect against distribution of Leukoreduced Red Blood Cells manufactured greater than eight hours from phlebotomy. Regional practice has staff physically place RBCs in storage within 8 hours and electronic creation of the product in NBCS would occur at a later time. Electronic records would look like they had been manufactured eight hours when they had not. In addition, there have been no recipient adverse reactions associated with any RBCs with electronic creation times > 8 hours." lam 12/20/02

84. QA failed to perform a thorough assessment of this problem in a timely manner. The North Central Region initially discovered this problem on 7/13/2001 and originally submitted a potential system problem request to BHQ on 9/6/2001. Then BHQ decided, on 10/3/01, that the problem with Red Blood Cell manufacture did not meet the criteria of a system problem. After another review of the problems, BHQ decided to open two system problems (#613 and 614) to address some of the issues. Then on 11/14/01 a decision was made to merge system problem #613 and 614 into one system problem (#616).

85. The original effectiveness check designed for SP 616 and approved by QA in 3/02 is inadequate because QA expects only a "90% reduction in the number of components identified as exceeding timing guidelines." This is an unacceptable practice for BHQ to expect nothing less than a 100% reduction. Note: The release of any product manufactured outside proper time limits would be considered an unsuitable blood product. lam 12/20/02

the release

86. QA has also failed to perform the effectiveness check designed for SP 616 within the established timeframe documented in SP 616. The established effectiveness check was designed to run SIP [redacted] 90 days after implementation and would only a select number of regions instead of assuring that all regions are in compliance. As of this inspection, SIP [redacted] has not yet been run and should have been by June 2002 when all established corrective actions had been implemented and signed off by the Executive Director.

87. BHQ failed to ensure that training for BSDs 62.210M and 62.200M was effectively and properly provided to

personnel in the regions. BSL 01-223, Failure to Prepare Red Cell Components within Timing Guideline, dated 10/10/01, was issued to inform the regions what the BSD requirements were yet BHQ did not require training on the BSL even after regions were having problems with the timing requirements for red blood cell manufacturing. In addition, the referenced BSL issued to the regional facilities on 10/10/01 identifies the incorrect BSD page reference for regional staff to use in order to review the BSD requirements for the receipt and triage of blood.

88. BHQ has failed to implement a software change to the NBCS to assist the regional users with manufacturing timing requirements, so that unsuitable products are not manufactured and ultimately released due to timing requirements during manufacturing. An NBCS Enhancement Request (#[redacted]) was submitted to the Development Center staff on 7/30/01. Yet, there have been two version releases, [redacted] in 10/01 and [redacted] in 8/2002, which do not include this change to the NBCS. In addition, a NBCS Change Request (#[redacted]) was submitted to the Development Center on 1/10/02 so that the regions will have the ability to print a report that will identify all components created outside of time limits. This change is not scheduled until NBCS version [redacted] which does not have release date at this time.

INCOMPLETE INVESTIGATION OF HOTLINE RECORDS:

In an 8/24/2000 letter, ARC described to FDA its progress in taking corrective actions to address the observations cited on the FDA 483 issued as a result of the 2/1-4/26/2000 inspection of BHQ. In that letter ARC stated that it would establish a "Hotline number" to "reinforce the ARC policy which requires all staff to report any potential violative activities, and to further ensure all staff understands its role in ensuring patient and donor safety and the need to follow legal requirements and ARC standards." ARC further stated in the letter that the hotline reports would be "thoroughly investigated."

89. There are no written procedures for receiving, investigating and correcting problems reported by employees through the "ARC hotline."

90. Quality Assurance is not responsible for reviewing and ensuring hotline records are appropriately investigated and corrective action taken. During the current inspection, FDA determined that QA did not have knowledge of all significant problems reported through the hotline, such as those addressing hematocrit deferrals and falsification of records.

91. When hotline reports (that could affect quality, safety, purity of blood products) are received indicating supervisors have been informed by the employee of the problem and failed to investigate and take corrective action, the investigation reports do not indicate that an appropriate investigation of the supervisors failure to correct the problem has been conducted.

92. There are no training records associated with investigating hotline reports for individuals reportedly responsible for directing the investigations and closing the investigations of the hotline reports.

93. The records for three hotline cases could not be located, [redacted] 1/3/01); [redacted] 1/29/01); and [redacted] 2/22/01).

94. During FDA's review of the Hotline records documenting investigation of employee problem reports, they were found to be incomplete, inadequate or lack complete corrective action. For example:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
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Hotline Case #[redacted]: An employee reported that a supervisor had changed the "create date" in the computer to indicate blood products had been properly processed when the blood products had not been in refrigerated temperature. The records of investigation are inadequate as follows:

a.) The employee who filed the complaint was not interviewed.
b) There was no investigation into the statement by the employee that after reporting concerns to supervisors, they were told the employees were responsible for correcting co-workers mistakes.
c) There was no investigation into the statement by the employee that blood products were dragged across floors, dried plasma was processed, blood components were left out of refrigerated temperature and the employees do not receive adequate training.
d) There was no investigation into why QA approved the "unload" without adequate documentation and investigation of why the "unload" was necessary.
e) There is no corrective action of the fact that QA is required to approve component "unloads" but had not been trained in the BSD 38.602M and had no QA SOP.
f) There is no basis for the statement in the case closure report indicating: "There is no evidence to indicate there is a widespread practice of falsification of documentation at the Region." A query was reportedly developed to identify components created outside of the "create session." There is no documentation indicating how this would identify any components that employees had "back timed." There was no review of "CDIS Component Unload Approval Form".
g) The 16 Red Blood Cells products identified by the employee as improperly processed were determined to be acceptable by the Material Review Board based on other employees "remembering" how specific blood components had been handled.

Hotline Case #[redacted]: An employee reported that a second employee changed the donor's answer on the Blood Donation Record to indicate the donor was eligible when in fact the donor was not eligible to donate since the donor admitted they had engaged in "high risk behavior" for AIDS. The BDR was "falsified" and the individual was accepted as a donor and not deferred as required. The records of investigation are inadequate since there is no basis to determine that the donor was and is eligible to donate as stated in the case closure memo.

Hotline Case #[redacted]: An employee reported that a donor had not been notified that a phlebotomist had stuck herself with a needle and then stuck the donor with the same needle. The blood unit was destroyed due to the potential for bacterial contamination and an employee was asked to tell the donor the unit was broken in processing or transport not about the potential needle stick. The phlebotomist was offered follow up testing. The donor was not deferred nor was the donor counseled and offered follow up testing until after the employee filed this complaint with the national Hotline. The records of investigation are inadequate since no determination was made whether other donors were not deferred after a result of potential needle sticks.

Hotline Case #[redacted]: An employee reported that a donor had an adverse reaction and the nurse did not take the donors vital signs because all of the equipment had already been packed in the truck. The records of investigation indicate the donor was contacted the following day and indicated he/she was feeling fine. There was no investigation performed nor corrective action was taken to determine why equipment required to be on site to care for donors was not available for use while donors remained at the collection site. There were two reported instances cited by the employee when donor vital signs had not been taken. In one case the donor was

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Mary J. Gordon, Investigator Linda S. Matthews, Investigator Stephani J. Wesley, Investigator	12/20/02

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
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contacted and asked to return to the blood center to have their vital signs taken. The records of investigation indicate one donor was contacted and asked to return to ARC to have their vital signs taken and there is no indication of any follow up with the second report. The case was closed with no corrective action or preventative action indicated

Hotline Case #[redacted]n employee that reported a training manager told employees to skip step four in a BSD because it takes too much time. The caller stated as a result donors sometimes place the confidential unit exclusion (CUE) sticker in the whole blood number field. The employees have been told to move the CUE sticker to the correct field compromising the integrity of the labeling process. The caller stated another BSD requires the container used to collect the blood be placed on a scale. For slow bleed the employees have been instructed to remove the container from the scale and place it on a stool. The records of investigation indicate the Director of Collections investigated the case and indicated the staff is never instructed to switch the WBN and CUE and that it is permissible to use a stool to check the blood flow providing the unit of blood is first placed on a paper towel. After the employee was provided this information the records indicate they were very dissatisfied with the response, the reporting process itself and called the hotline a "farce." The caller stated the Director of Collection should not have conducted the investigation because she was the one violating the policies in the first place.

Hotline Case #[redacted]: An employee reported that the blood donor record (BDR) is not thorough enough and donors should be asked if they are taking certain medications. The employee stated when she has asked additional questions she is told by her supervisor not to ask additional questions of the donors. The records of investigation indicate the region follows all directions in the BSD and the issue of having the BDR changed to include more stringent questioning should be directed to QSS at BHQ. There is no record indicating the issue was forwarded to BHQ for follow up.

Hotline Case #[redacted]: An employee reported that the BDR was changed a few years ago and there is a question asking donors if they have any medical condition but not a question asking donors what medications they are currently taking. The caller stated some donors are taking medication but do not consider themselves to have a medical condition. The response indicates the MACS BDR questions are closed ended. The current BDR does not have a general medication question but donors are asked about several specific medications. There was no investigation performed to determine if donors who should be deferred are being accepted due to the limitations of the questioning.

Hotline Case #[redacted]: An employee reported the controls for the hematostat machine are run before the instrument is moved to the collection site if the site is not air conditioned. The response indicates the hematostat machines used by quality control have temperature limitations and on very warm days are quality controlled at the region. This alternate procedure was approved by BHQ. There is no record of investigation as to the potential effect not running the controls under the same condition of use for the blood samples being tested.

Hotline Case #[redacted]: An employee reported the donor collection site ran out of test tubes used to collect blood samples for NAT testing. They were instructed by the manager of donor services to use NAT tubes that had been placed in a biohazard container. The region investigation determined that the tubes used were voided tubes from previous collection sites that that had been placed in "empty/clean sharps containers as they were voided." The removal of the labels and the use of these test tubes had been approved by the Manager of Donor Services, the Collections supervisor and QA officer.

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Hotline Case #[redacted]: An employee reported that another employee on a mobile unit continued to take blood from two donors after they had passed out. The caller believes that the other employee was more interested in obtaining units of blood rather than the well being of the donor. The called stated that the other employee said the donor felt fine and she did not want to get a "quantity not sufficient" for the collections. The regional investigation only addressed one incident and not the other and did not address why the employee felt so compelled to continue with collection when the donor was having a reaction.

LABELING MIX UPS:

95. BHQ has failed to implement adequate labeling procedures to prevent mix ups such as discrepant blood types, reported and determined to be caused by test tube mix up at collection; two different blood donor records with the same whole blood number; the whole blood number on primary bags not matching the whole blood number on the satellite bags and the mix during the sterile docking procedure of filters used for the leukoreduction of blood components. During the previous inspection of BHQ in April 2000, system problem # 419 was reviewed. The labeling issues were determined to be a system problem in April 1998 and several changes to BSD's were proposed as corrective action. There was no corrective action implemented by the end of the inspection in April 2000. Since that time SP #419 was closed on 7/10/00 when the corrective action was completed and BSD's 51.120M and 52.101M were issued.

96. Two months after closing SP 419, SP 501 was opened as a potential system problem on 9/13/00 when the Acting CEO requested an investigation of labeling problems indicating mislabeling of units is the most serious kind of error because it can result in significant harm to the patient. On 9/27/00, the PSP was determined to be a SP and was assigned SP #501. The record indicates that the BSD changes made to correct SP #419 do not address labeling mix ups that occurred later in the manufacturing process. The records for SP#419 do not indicate the SP was ever reopened. The file for SP #501 then indicates the issue was moved to SP #545 on 4/29/02 (during this inspection) 18 months after the SP was identified. SP 545 was limited to the investigation of labeling problems during leukoreduction.

97. SP #545 was opened 9/20/00. BHQ determine during review of SP #419 that labeling problems during leukoreduction was a separate issue. However, SP #419 was closed on 7/10/00 and does not indicate that leukoreduction was identified as a problem. The root cause of SP #545 was later identified to be a failure to follow the BSDs already in place and insufficient space provided at the workstation to allow for processing one unit at a time. BSL 01-123 was issued 6/22/01 requiring regions to reassess the performance of all personnel to follow the procedures. The implementation date was December 28, 2001 at least 15 months after the problem was identified. On 5/24/01, BSL-01-91, "Use of Critical Control Points to Prevent Labeling Errors Associated with the Sterile Connect Filter Methodology," was issued with an implementation date of 9/28/01. On 6/22/01, BSL 01-123 was issued to extend the implementation date by an additional three months (12/28/01).

98. During the time of the extended implementation date (9/01-12/01) for BSL 01-123 in SP #545, there were at least three additional occurrences of labeling errors that happened during the leuko-reduction process (BPDR # 2001-042-002154, 2001-020-004254, and 2001-017-003996).

99. The corrective action for SP #545 included a cross-functional meeting on 12/14/00, 2000 to determine conversion plans for a switch from dock-on in line filters. The resolution of that meeting was a first phase reduction of sterile dock to 58%. As of this inspection, thirty-two of 36 regions (or 88%) continue to sterile dock filters.

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100. Corrective action for SP #545 included evaluating regional space needs due to "insufficient space at workstations". There was no written evaluation available during this inspection.

101. SP #545 contains a memo dated 4/25/02, stating there were no violative Blood Product Deviations received and associated with whole blood numbers mix-ups occurring during leukoreduction using the sterile docking device. BPDR # 2002-027-001527 occurred 4/3/02 in the Greater Alleghenies Region and was reported in BHQ's Weekly BPD summary for 4/7 – 13/02. BPDR #2002-027-001527 reported that a unit of Red Blood Cells Leukocyte Reduced was labeled as A Positive, but in fact the unit was actually B Positive. Investigation of the deviation found that there were at least 16 other units that were implicated and recalled. The cause of the deviation was failure to follow procedures for leukocyte reduction resulting in a mix up of whole blood numbers.

102. At least two regions did not implement BSL 01-123 by the required date of 12/28/01 (Central Plains implementation date of 1/2/02 and Greater Ozarks 1/24/02).

103. SP #562 was opened 2/26/01. The record indicates that during review of SP #419 (SP #419 was closed 7/10/00) it was determined that mislabeling of units during special collections (autologous) should be managed as a separate issue. On 3/14/01, PSP #562 was determined to be a SP. The corrective action plan indicates training needed to be enhanced, an education letter needed to be sent to physicians, and a requirement for a second staff review of all forms needed to be added to the BSD. As of 4/1/02, the SP file indicates the BSD and training changes are on target for the 2nd quarter of 2002. There is no reference to the educational letter to be sent to physicians.

104. SP 563 was opened 2/26/01. The record indicates that during review of SP 419, which addressed mislabeling of bags, tubes and BDRs and review of effectiveness checks, the root cause was not truly identified and the process would be reevaluated. The corrective action plan included additional changes to the BSD; however, because the BSDs had just been changed the corrective action would not be implemented until the 1st quarter of 2002. The record currently indicates the changes to the BSD are on target for the 2nd quarter of 2002.

DONOR DEFERRAL ASSERTIONS:

When a donor is either temporarily or indefinitely deferred, a code is used in the NBCS to assert or apply the reason for and the length of the deferral. The specific reason for deferral must be tracked so that blood products can be handled appropriately.

[redacted] TIMING PROBLEM (DONOR DEFERRAL ASSERTIONS)

105. BHQ fails to have adequate control of donor deferral assertions. On 7/6/01, a region ([redacted] case #344493) reported that the auto assert logic did not run and assign the appropriate code [redacted] to the donor record for a donor who had a positive test for HIV. An investigation revealed that there was a "bug" in the system due to a timing problem. The regions were provided with a manual workaround on 7/13/01. The "bug" is not currently scheduled for correction. In addition to the potential for erroneous release of subsequent blood components from these donors, the donor notification process is not initiated.

106. BHQ failed to complete corrective action. A query (SIP[redacted]) was run on 7/26/01 to identify donors who had a positive test result without the appropriate donor deferral assertion. The query identified approximately 1500 records that did not have the corresponding assertion from the implementation date of NBCS to 7/26/01. The records of

the query do not identify the query number, region or the individual reviewing the results. No records of investigation show the donors have been deferred or that any components erroneously released have been recalled. Reportedly the SIP results were reviewed by a [redacted] contract employee, and, it was during this review, an additional problem was noted with the auto assert logic and NAT testing.

107. BHQ failed to monitor the corrective action. In February 2001, the query (SIP #[redacted]) was run a second time and identified approximately 300 new records that had a positive test result and did not have the corresponding assertion. There are no records of the review of these query results. There was no investigation to determine the reason the regions were not following the workaround.

108. BHQ failed to ensure complete corrective action. During this inspection, the query (SIP [redacted] was run on 4/25/02. At this time, six regions were identified as not following the workaround. Nine months after the problem was originally identified, a decision was made to run the query (SIP [redacted]) on a monthly basis until the "bug" is resolved in NBCS release [redacted]. The deviation reports for Central Plains and Southern Regions were identified as LCTs (log, correct and trend) and indicate no investigation was conducted and no preventative action was taken by the regions. In addition deviation #2002-055-000967 (5/30/02) from the Greater Ozarks Region indicated that the region identified, while performing the review, 886 donors with [redacted] assertions dating back to 10/21/00, which they had failed to resolve or defer.

[redacted] – (DONOR DEFERRAL ASSERTIONS)

109. On 7/16/01, another region reported in [redacted] case #347566 a problem that occurs when a donor has an assertion (deferral) code applied automatically. The investigation revealed the problem was limited to five regions on [redacted] and occurred only when the donor had a blood type reported as [redacted] (no test determined). NBCS would only apply the [redacted] and not the assertion/deferral. A manual workaround was provided to the regions on 7/19/01.

110. A query (SIP #[redacted]) was developed to identify donors with blood types reported as [redacted] so that the donors' record could be investigated to determine whether an auto-assert/deferral category was ever applied. SIP #[redacted] was run on 8/3/01. BHQ had no record of the review performed on the results of the query.

111. [redacted] case #347566 indicates the query is not scheduled to be run on a regular basis because the process guidance addressed in BSL 01-145, 7/19/01, Revised Guidance for Reviewing [redacted] Results, will ensure investigation despite repeated findings of failure to follow work-around.

112. BHQ failed to properly investigate the error. Software engineering determined the defect was due to "NTD" not being considered a valid blood type in an NBCS table ([redacted]); however, there is no record of an investigation to determine why the [redacted] software could have been released without the correct table.

[redacted] (DONOR ASSERTION)

113. Reportedly, on 7/13/01, ([redacted] case #347077) during the review of the query SIP [redacted], it was discovered that the auto assert logic in NBCS did not run for NAT positive results and did not apply the appropriate "[redacted] assertion" to a donor record. This would prevent the donor notification from taking place, and allow the individual to make a

subsequent donation. This subsequently donation would prevent retrieval of any in-date blood components. This query reportedly identified 25 donors in ten regions over an unknown period of time.

114. BHQ's investigation revealed the "[redacted]" assertion/deferral was not added into the auto assert logic in NBCS when NAT was added; however, there is no record of an investigation into the software failure.

115. A query (SIP with unknown number) was run to identify NAT only results. A summary was available; however, the original query records are not available. In addition, the date the query was run, the inclusive dates of the query and the identity of the individual reviewing the results are not available.

[redacted]ASSERTIONS (DONOR ASSERTION)

116. On 5/30/2002, a region identified that there were 886 donors with [redacted]assertions from as far back as 10/21/00 and four [redacted] assertions from as far back as 12/15/98 which were not resolved. BSD 43.301M requires investigation of the reports on a daily basis. During the current inspection, there was no record available of investigation of this problem to determine whether it was occurring in other regions. There was no investigation into the failure of QA to identify the problem from 7 to 41 months.

117. Deviation #2002-055-000888 (5/29/02) and deviation number 2002-055-000967 (5/30/02) from the Greater Ozarks Region indicates the regions identified 886 donors with [redacted]assertions dating back to 10/21/00 which were not resolved. There was no record available during this inspection of BHQ's investigation of the regions' failure to follow BSD 43.301M.

HEALTH HISTORY ASSERTIONS (DONOR ASSERTION)

118. On 11/13/00, a region identified a potential hazard when a deferral reason was entered into[redacted] in NBCS; however, the deferral code or assertion was not assigned to the donor as expected. The system is supposed to automatically apply the deferral assertion, which will then identify any blood components collected from this donor as unacceptable. An investigation revealed that a user could exit the record before the deferral assertion is applied, resulting in failure to defer the donor. A query (SIP) was developed to identify donations in all regions since the implementation of NBCS which had a health history deferral reason without the associated assertion.

119. An undated, unsigned summary of findings indicates that there were 796 records with the correct reason for deferral without an assertion initially identified. Review of these records resulted in 27 recalled components. This summary indicates there were at least six other reasons for the incorrect records identified by regions; however, there is no record of corrective action being implemented. The reasons include failure of supervisory review process migration issues from [redacted] and assignment of other tasks which allowed for interruption during the review process.

120. The query (SIP) was run once a month until July 31, 2001 when NBCS vs. [redacted] was installed in all regions. This version prevented the user from exiting the record incorrectly. During the seven months that the query was run, donor records with the correct reasons for deferral with no assertion/deferral continued to be identified as follows: (December 00/January 01, 15 records), (February 01, 2 records),(March 01, 10 records resulting in recall of one component), (April, 01, 7 records), (May 01, 6 records), (June 01, 6 records), (July 01, 10 records). BHQ has no record of

an assessment of the reason the incorrect records continued to be created despite the regions being informed of the limitation of the system.

121. On 8/22/01, BSL 01-178 was issued. This BSL discontinued the monthly record reviews. The BSL states based on the release of NBCS vs. [redacted] the record reviews are no longer required despite the fact there were other reasons for the incorrect records being created that had not been addressed in a corrective action plan and the fact that the reasons the records errors had continued from December 00 to July 01 were never determined.

122. During the current inspection on 5/17/02, a "second operational review" of the data from all runs of the query was reportedly completed. This summary cites issuance of a BSL and changes to two BSDs as corrective action. There is no record of effectiveness checks being performed on these corrective actions.

[redacted] ASSERTIONS (DONOR ASSERTION):

The [redacted]") assertion is used to identify donor records for which additional Whole Blood Number information is not available in NBCS. The assertion informs the user that if they are investigating lookback or suspected post transfusion disease cases, the [redacted] system must be searched for additional component information.

123. On 3/3/99, one region converting to NBCS noted on conversion reports that 96 donors did not have the [redacted] assertion after migration to NBCS. SIP [redacted] was developed and the records were corrected on 7/1/99. There is no record of investigation to determine if other regions were affected by the same problem.

124. On 7/25/01, BSL 01-150 required regions to review their current database for any [redacted] deassertions (removal of [redacted]) and to determine the reason for the deassertions. The only reason the [redacted] assertion should be deasserted would be during record merger; however, it is then added back to the record. There is no record of how this potential problem was identified to determine if the corrective action outlined in the BSL was adequate.

125. BHQ did not review the regional deviations. During this inspection, we reviewed the deviations and noted that 18 regions identified inappropriate deassertions (removal) of the [redacted] assertion. Two regions never completed a deviation report, as required by BSL 01-150. Ten of the 18 regions did not perform any root cause analysis or preventive action.

126. One region reported using the assertion [redacted] to identify donors in another region when they shared blood collection responsibilities, rather than for identifying donors who may have necessary donation information in the [redacted] system. This was not investigated. The regions that investigated the deviations reported temporary staff had inadvertently deleted the assertions, and some deassertions of [redacted] occurred while trying to delete an unrelated assertion. There is no record of any investigation of the procedures for processing assertions/deassertions to determine the impact on other assertions in the system.

127. One region reported that three months after the original review required by BSL 01-150, it identified 15 additional donors that had the [redacted] assertion removed incorrectly. There was no investigation into the reason these 15 deassertions were not identified in the original review.

AUTOMATIC ASSERTION [redacted] (DONOR ASSERTION)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	[signature]	Mary J. Carden, Investigator Linda S. Matthews, Investigator Stephany J. Wesley, Investigator	12/20/02

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
6000 Metro Drive, Suite 101 Baltimore, Maryland 21215	FEI NUMBER: 1000123507
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Ramesh Thadani, Executive Vice President and Chief Executive Officer	
FIRM NAME American National Red Cross/Biomedical Services	STREET ADDRESS 1616 Fort Myer Drive
CITY, STATE AND ZIP CODE Arlington, Virginia 22209	TYPE OF ESTABLISHMENT INSPECTED National Headquarters of a Licensed Blood Bank

BHQ has failed to adequately control changes made to automatic assertion tables. On 7/19/01, a region reported that a donor who tested positive for HBsAg and anti-HBc did not have "[redacted]" or "[redacted]" automatically asserted as required.

128. BSL-152 was released to the regions on 7/31/01 to explain the system limitations and provide a workaround. The regions were informed that a query would be developed and that regions identified as having incorrect records would be contacted. The query (SIP [redacted]) was not run and reviewed until February 2002, six months after the problem was identified.

129. The bug report [redacted] for this problem indicates it was caused when the "[redacted]" assertion was added to the system. The investigation report indicates that the HBsAg application was properly deleted from "[redacted]"; however, the [redacted] table and the [redacted] in the regions database contained the HBsAg in the application column of the table for [redacted]. There is no deviation report for how this error occurred or what corrective action was taken.

130. The query (SIP [redacted]) results provided during the inspection are not identified with the query or SIP number run or the date the query was run. The required start date and end dates of the query were from the date the individual region went live on NBCS version [redacted] to the go live date for NBCS [redacted] when the software fix was installed. The dates used for each region as shown on the query results do not match the dates identified in [redacted] case #376588 for the "go live" dates for each region.

NBCS AUTOMATIC ASSERTION TABLES (DONOR ASSERTION)

BHQ has failed to maintain adequate documentation. During the previous inspection in February-April 2000, we noted several problems with the automatic assertion tables. BHQ had not performed a comprehensive review of the tables to ensure that any additional limitations would be identified and corrected.

131. In the ARC response to the FDA 483 dated 5/15/00, ARC reported that "During this time a complete assessment was undertaken to determine any additional deferral assertion limitations. One additional limitation was identified and the third and last BSL, BSL 99-030, was released immediately." During the current inspection, we requested a copy of this evaluation for review. There was no record of this comprehensive assessment. We were provided with a one-page memo dated 9/22/00 indicating that "A comprehensive review of the NBCS Automatic Assertion tables was completed in 1999 to ensure any additional limitations would be identified. The tables were compared to the deferral criteria listed in BSD 43.104M, Donor Deferral Management." The results portion of the memo states "No additional discrepancies were identified at that time."

AUTOMATIC ASSERTION ([redacted]) (DONOR ASSERTION)

132. BHQ has failed to adequately control changes made to the automatic assertion tables. In June 1996, the national testing laboratories changed from the HCV [redacted] test to the HCV [redacted] test. The assertion [redacted] was replaced in the test result assertion table, the auto-assert action tables and other tables by [redacted]. The CR (change request) [redacted] indicates that after some database changes are made in one region, a second change request will be submitted to delete the [redacted] assertion from the [redacted] table.

133. This second change request was not submitted. On 10/18/99, a region reported that a donor was not automatically asserted to the [redacted] assertion as expected. The investigation revealed this occurred because the [redacted] assertion

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6000 Metro Drive, Suite 101 Baltimore, Maryland 21215	FEI NUMBER: 1000123507
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was removed from the [redacted] table in 8/96 by design and the [redacted] table still has the [redacted] as a valid assertion. There is no record of investigation to determine why the second change was not made.

134. [redacted] case #148779 indicates the corrective action plan would include the development of a SIP to correct the tables and the development of a SIP to identify donors currently with assertion [redacted] and positive test results. These results would then be used to determine if a donor file check is required. Once the tables have been corrected, the SIP would be rerun. The problem was identified 10/18/99, and the tables were corrected 1/27/00. SIP [redacted], developed to identify the donors, was not run until 4/17/00 and, as a result, the requirement for a donor file check was not determined for six months.

135. On 2/23/00, during the development of the SIP [redacted] the record [redacted] case #148779) indicates the testing on the SIP was waived. There is no record of QA approval of the waiver.

136. The record of investigation [redacted] case #148779) indicates that during the investigation the [redacted] were reviewed. At the time, the charts for [redacted]" were set at the assigned value of [redacted]" at the time of collection, no NBCS action and when [redacted]" is asserted as a result of test results for the current donation, the assigned value is [redacted], does not release. This would indicate that components could be released if the [redacted] assertion resulted from a previous donation. The record indicates a "test" was performed, and the conclusion was that product would not be released. There is no record that this inconsistency was resolved.

137. Records which indicate SIP [redacted] (unvalidated) was run on 10/22/00 were provided. There is no record of the reason the SIP was run at this time and no record of review of the results.

138. On 4/3/01, a region reported ([redacted] case #312914) again that a donor was not automatically asserted to the [redacted] assertion as expected. The investigation indicates that SIP [redacted], which corrected the problem initially, was being developed at the same time as a SIP for NAT testing. In September 2000, when the SIP for NAT testing was applied, it overwrote lines of logic for the [redacted] assertion and replaced it with the logic for NAT testing. There was no record of an investigation including root cause analysis and preventive action taken as a result. We were informed that a deviation was probably written; however, nothing was provided during this inspection. When this problem was identified a second time, the regions were again provided with a workaround (BSL-01-167); however, there is no record of a SIP such as SIP [redacted] being rerun from April 2001, when the problem was introduced, until October 2001 when it was corrected in NBCS vs. [redacted].

SOFTWARE CONTROL

[redacted] Software

139. BHQ failed to complete corrective action in a timely manner. On 10/10/00, a region reported a potential hazard when test results were electronically transferred as "blood type O+" when the actual test results were "blood type A+." The ALT test result transferred as "34 IU" when the actual result was "9 IU." This was due to the fact the [redacted] software had been configured incorrectly. The potential hazard summary indicated, by 11/17/00, QSS would determine if a retrospective record review was necessary. This was not done until 3/14/01, four months after this date and five months after the problem was originally identified.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
6000 Metro Drive, Suite 101 Baltimore, Maryland 21215	FEI NUMBER: 1000123507
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Ramesh Thadani, Executive Vice President and Chief Executive Officer	
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140. BHQ failed to complete corrective action. The query developed to perform a record review (SIP[redacted]) only identified "[redacted]" assertions and did not identify "[redacted]" error messages. There is no documentation of this decision to limit the query. During this inspection, BHQ determined that a query could not be developed to identify the "[redacted]" error message. The [redacted] error log and the manual records for the "[redacted]" are not maintained and, therefore, a manual retrospective record review could not be performed. There has been no investigation of the failure to maintain these records.

141. BHQ failed to maintain adequate documentation. [redacted] case #254426 was initially handled as a "potential hazard" on 10/10/00. On 10/11/00, the case was downgraded from a potential hazard which means that the user must investigate all error messages. A potential hazard summary was approved on 12/01/00, and there is no record indicating when the case was again considered a potential hazard. During this inspection, it was determined that the BSD and additional reference material did instruct the user to review error messages, but does not instruct the user to review all test results for the unit. It would be necessary to use this method as a workaround.

142. BHQ has failed to adequately control software. There is no deviation report or record of the investigation into the configuration problem in the [redacted] software. Reportedly the software was simply used "out of the box."

143. BHQ failed to implement corrective action. The investigation revealed that there is a problem with the transfer of ALT test results. The investigation states that an "enhancement" to correct this problem would be entered into the enhancement database. This "enhancement" has not been implemented.

144. BHQ failed to implement corrective action. The case indicates that the corrective action would include adding some additional [redacted] screening of error messages from [redacted]. This was never done and there is no record of any decision made not to implement this corrective action.

145. BHQ has failed to adequately review records relevant to MDR (Medical Device Report) submissions. The records of the MDR decision do not include the reason that this issue not reported as an MDR. The SOP requires that the decision be documented. The case notes indicate that the problem was the [redacted] software was configured to keep files which are interrupted when transferred when the "documentation" states that they will be discarded.

146. BHQ failed to ensure corrective action in the regions. There is no record of a review of the regional results, deviations or analysis of why the discrepancies occurred. Missouri Illinois Region reported 34 discrepant test results; however, no deviation report was provided and no investigation occurred. The initial record count indicated as many as 406 records in one region. The query output reported the most records identified for any region was 77.

[redacted]:

147. The [redacted] lists 37 cases of software changes made in response to software problems and the appropriate test cases and test procedures. During this inspection, we requested the deviation reports or records of investigation for the 37 cases including the root cause and preventative/corrective action. BHQ provided no reports of the investigation. The only record made available was a two-page memo prepared during the inspection which lists a root cause for six of the software problems and preventive/corrective action for three of the six software problems listed.

[redacted]

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148. The [redacted] control the release of products in [redacted] The "X[redacted]" assertion was added in NBCS vs[redacted] to be used as a Creutzfeldt-Jakob Disease deferral assertion. The [redacted] assertions were added in NBCS in version [redacted]. These assertions were added to flag DDR hits. In both cases, the change request (CR) did not correctly documen[redacted] to which the assertions needed to be added. Once this problem was identified, it was assessed to be a potential hazard since it would allow the release of unsuitable plasma for fractionation. The preventive action indicates the [redacted] in NBCS are being redesigned to "facilitate review of changes." The NBCS[redacted]s scheduled for release in fall of 2002. There is no record of an investigation to determine why the original change requests were incorrect or why testing and validation did not identify the problem before the software was released.

SOFTWARE CONTROL

149. BHQ failed to establish adequate control of software configuration settings, installation qualifications and validation, despite deviations and reports from the regions indicating the need for additional controls.

150. [redacted] case #429404, dated 3/20/02, indicates an NTL reported that "somehow" the configuration affecting the cut off values for ALT test results was changed. There is no record of investigation including no review of who has access to make changes to the configuration, how the inadvertent change was made or how it could be prevented in the future.

151. Deviation #2001-090 000070, dated 2/16/01, indicates six[redacted]s were used in production without being tested as required by BIS procedure BISS005.

152. [redacted] case #283184 indicates that on 1/9/01 the user reported the [redacted] system did not correctly recognize IND (indeterminate) test results for antibody screening. As a result, false negative test results could be released.

153. [redacted] case #287736 states the current [redacted] configuration for STS (serological test for syphilis) is set to expect one retest result for the PK 7200 when the initial test result i[redacted] (initially reactive). If one repeat is [redacted] (non-reactive), the final result transfers as [redacted] (positive) into NBCS, when the correct interpretation should be [redacted]. The root cause indicates the [redacted] operational qualification and validation plan did not contain sufficient details for validating the configuration values (number of retest results required).

154. Deviation #2001-090-000014, dated 1/11/01, indicates that during installation of [redacted] a configuration field for the hepatitis test incubation time was set incorrectly. The software was put into production with this error.

155. Deviation # 2001-090-000045, dated 1/26/01, indicates the software for [redacted] release [redacted] production was not the same as the software tested for release.

156. Deviation #2001-090-000037, dated 1/29/01, indicates the package insert decision logic for STS (serological test for syphilis) was not correctly configured.

157. Deviation #2001-090-000058, dated 2/26/01, indicates there were configuration errors in the [redacted] database for reporting [redacted] results.

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158. Deviation #2001-090-000368, dated 11/30/01, indicates it was noted that the [redacted] for NBCS applications considering properties for specific products were changed in one region.

[redacted]N PROPERTY

159. BHQ fails to have an adequate process in place to correctly process [redacted]n properties. A [redacted] property is an attribute that provides additional information about all the components associated with a specific donation. For example: "[redacted]" is a [redacted] property assigned to all components from a given donation when the donor has a questionable medical history. Some [redacted] properties such as "[redacted]" when assigned to the blood components are intended to prevent the release of the unsuitable product. [redacted] properties are added in either "[redacted]" where the [redacted] properties are added to one whole blood number or "[redacted]" where the [redacted] properties are added to a series of whole blood numbers.

160. BHQ failed to implement adequate corrective action. During the previous inspection in February-April, 2000, a problem was identified in the use of [redacted]. The problem in [redacted] case #96820 identified the fact that [redacted] properties are not added to components that have been shipped, if added in group operations. If the product is returned and a property that would make the component unsuitable had not been added, the product could be erroneously released. ARC failed performed a retrospective review. The ARC response to the FDA, dated 5/15/00, indicates a record review was considered but determined to not be required, because the existing retrieval process would have already caught the components returned and released without the appropriate property. ARC records do not state how all components such as outdates, short dates, overstock products would be identified as unsuitable through the retrieval process.

161. BHQ failed to conduct an adequate investigation and to perform corrective action in a timely manner. A problem was identified on 5/19/97 ([redacted] case #13208), and 11/03/97 ([redacted] case #24107) in the use of "[redacted]." The [redacted] property "[redacted]" was not added to all components from a single donation. At the time, the problem was identified as a "bug", the case was downgraded to "routine" and the case was closed indicating all future problems would be referenced to this case. No user instructions were provided. Additional [redacted] cases identified a continuing problem on 11/03/97([redacted] case #24107), 3/29/99 ([redacted] case # 100622), 3/28/00 ([redacted] case # 192362) 4/17/00, ([redacted] case #197857) 6/27/00, and [redacted] case #219911). Not until approximately three years later on 6/23/00 [redacted] case # 218639) was a review performed to determine if the problem could also be occurring with [redacted] properties other than "[redacted]." In June 2000, the problem was finally identified as a potential hazard because all [redacted] properties were affected. The regions were provided with a workaround, and a query (SIP [redacted]) was developed to identify any erroneous releases.

162. BHQ failed to properly complete corrective action. [redacted] case #218639 (6/23/00) indicates the query (SIP [redacted]) will initially be provided to the regions before and after it has been validated by BHQ; then each week until a software "fix" has been provided to all regions; and then as an effectiveness check once the "fix" has been installed. The records of the query are not always identified with the query number, the dates they were run, the identification of the individual reviewing the results, the date they were reviewed, and the results and conclusions. There are no results of the regional follow up.

163. BHQ failed to adequately review and explain discrepant information. [redacted] case #218639 indicates there were no erroneous releases identified. However, a record identified as a 6-28-00 "[redacted] property query" does indicate there was an erroneous release.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
6000 Metro Drive, Suite 101 Baltimore, Maryland 21215	FEI NUMBER: 1000123507
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Ramesh Thadani, Executive Vice President and Chief Executive Officer	
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164. BHQ failed to document QA review and approval. [redacted] Case #218639, indicating that query (SIP [redacted] would be used as an effectiveness check, was closed on 11/17/00. There is no record of QA review and approval, no time period set for completion of the effectiveness check, and no record of how many times the query should be run. The query was then completed on 1/3/01, 3/14/01, and 6/27/01. There is no record of the QA review of the query results. The results indicate a change in the record count on 1/3/01 for the "[redacted]" property in the Southwest Region with no investigation.

165. BHQ failed to have adequate control of software changes. NBCS vs.[redacted] (Implementation date October, 2000) contained the "fix" for the problem in NBCS regarding [redacted] properties. That "fix" added a [redacted]. The "fix" was omitted from the next release NBCS vs. [redacted] again allowing erroneous release of product. This was not identified until testing was performed on NBCS vs.[redacted] in June, 2001. BHQ then required the regions to utilize a workaround. A query (SIP [redacted] was developed to identify any erroneous releases.

166. BHQ again failed to complete corrective action. The records of the query indicate the query run was SIP [redacted] not SIP [redacted] as required. When the query was first run on 7/5/01, it was supposed to cover from 3/14/01 to the present, but there is no evidence that it did. The records of the query do not include the date they were reviewed and the results and any conclusions. Reportedly, the query (SIP [redacted] was also run on 7/21/01 and 7/31/01; however, there are no records of the results. There is no justification for the query not being run after 7/31/01 and no planned effectiveness monitoring.

167. BHQ has failed to promptly identify a potential hazard. On 5/9/01, a region reported another potential hazard when adding [redacted] properties through [redacted]. When a property is added in [redacted] and the property is already on the donation for another reason, the user does not receive a message alerting them as occurs when the addition is made in [redacted]. As a result, a component could be erroneously released before all reasons for the property are resolved. [redacted] case #325682 was not recognized as a potential hazard and a workaround was not provided to the regions until 7/12/01. In addition, BHQ determined that a query could not be developed to identify any erroneous releases or monitor the effectiveness of the workaround. Despite this, the "fix" has not been scheduled for any NBCS release.

168. BHQ failed to provide adequate user instructions to the regions. On 10/8/01, a region reported a property added in [redacted] was not applied to all products created. Neither the region nor BHQ recognized this as a "bug" previously identified in 1997 for which a partial software workaround had been provided. The regions were not provided with a manual workaround for the problem until approximately three months later on 1/23/02, when they were instructed on application of the property to prevent the "property check from failing." BHQ put no workaround in place to ensure [redacted] properties are added only to correct the problem if identified.

169. BHQ has failed to complete corrective action. On 1/18/02 and 1/25/02, regions reported that the system did not properly identify the individual responsible for adding the property and, in some cases, the date it was added. The problem was identified as a "bug" present from the original implementation of NBCS. [redacted] case #410772 (1/25/02) indicated that the need for communication to the regions would be determined. The case was then closed with reference to [redacted] case #408197 (1/18/02) closed on 4/12/02 with no determination about communication to the regions. The "bug" is reportedly scheduled/proposed for correction in the next release of NBCS version [redacted] however, there is no record of

instruction to the regions to maintain manual records until correction.

SYSTEM PROBLEMS

BHQ has failed to ensure issues identified during the previous FDA inspection in April 2000 regarding the timeliness of evaluating and correcting system problems have been corrected. The corrective action is being tracked in Deviation #2000-090-000150 and #2001-090-000269.

170. Deviation #2000-090-000150 was opened on 4/26/00. The deviation report indicates BSL 00-132 was implemented on 8/3/2000. This BSL defined the new process for managing system problems. In addition, an in-process review (IPR) was to be performed by 12/31/00 to determine if the BSL had been fully implemented and all timelines were being met. The corrective action was not approved by QA and the department head until 2/15/01.

171. In December 2000, an IPR found that the problems were not completely corrected and that additional corrective action was warranted. BHQ's only record of this IPR provided is a Power Point presentation dated 12/18/00. The additional corrective action indicates that an LOP (local operating procedure) would be developed for QSS for managing system problems and that another IPR would be performed 4/15/01. The only record of this IPR provided is a Power Point presentation dated 5/1401. This record indicates, "Performance has not significantly improved since IPR in December 2000." Additional corrective action in the deviation report #2000-090-000150 indicates the long term corrective action included developing a BSD by 5/1/01 and performing another IPR by 8/1/01.

172. Deviation #2001-090-000269 was opened on 6/29/01 when a review of system problems on 5/23/01 revealed non compliance with LOPs 30.104 and 30.109 on system problem management. This deviation report indicates this was a known problem and that the "System Problem System is currently under revision..."

173. On 8/23/02, the preventive action plan for deviation #2000-090-000150 was again modified. The record indicates that BSD 92.104 was implemented on 2/28/02 and indicates that there was insufficient data to determine if the new BSD was effective in addressing the management issues cited in the FDA observation related to system problems. Another review was scheduled for 12/31/02, over 21/2 years after the FDA observations were made in the February-April 2000 inspection.

The following observation relates to specific system problems:

174. A potential system problem was submitted on 5/21/01 when six units of leukoreduced platelets were erroneously released prior to the completion of the prelableing process. The region noted the problem was due to the use of the [redacted] system which does not have an option to control the labeling process by whole blood number or collection date as the previous [redacted] did. On 6/13/01, it was determined not to be a system problem. The record indicates that a Biomedical Information Systems (BIS) enhancement would be evaluated for inclusion in a future software release. There is no record of an enhancement related to this problem. There was no rationale for why this was not a system problem. On 5/9/02 during this inspection, a memo was written that reportedly summarized the discussion that occurred on 6/13/01 (11 months earlier) and concluded that the region failed to follow the process as outlined in several BSDs.

175. BHQ failed to properly investigate system problem #561. On 2/24/01, the Southwest Region identified a

potential system problem. The region noted that BSL 00-130 provided instructions on handling components when identification discrepancies cannot be resolved in seven days, but provided no instructions on handling the donor. The region noted that the association of the donor record is needed to apply the deferral codes, perform donor notification for positive tests, and track donor safety issues, such as donations within 56 days. The problem was identified as a significant regulatory risk by the region.

176. On 3/14/01, the problem assigned system problem #561 was determined by BHQ not to be a system problem. The record indicates the reason as "The blood product will be destroyed if no resolution is made. The donor will get re-tested if he/she donates again." This rationale fails to address several issues: the fact that the donor should not be allowed to donate again; that the donor will not be notified; and that the region will not be able to prevent the donor from donating within 56 days. The record also indicates that "[t]he Sr. Director of Operations Design will work with the region and investigate if other regions have the same problem." There is no record of this investigation being completed.

177. The records for SP #561 indicate that on 5/16/01 and 9/25/01 additional rationales for this system problem were approved. The rationale approved on 5/16/01 indicates that BSL 00-130 was part of the corrective action yet this same BSL was cited, on 2/24/01, by the region that submitted the potential system problem as, lacking the information necessary to correct the problem.

RELEASE OF INCOMPLETE TEST RESULTS SP #623 AND #624

On 12/20/01, release of incomplete test results occurred at the Dedham National Testing Laboratory (NTL) and the Philadelphia NTL. The samples were sent from Detroit NTL and Philadelphia NTL for repeat testing after testing initially reactive (HBsAg) In both instances, the NTL tested the samples as a single retest instead of in duplicate and transferred the incomplete test results of negative to the customer.

178. The SP record has no documented rationale for failing to perform a review of all transferred test results.

179. BSL 02-034 was issued 3/1/02 to correct the problem, but did not include critical parameters identifying which NTL would be responsible for review and release of the test results when two NTLs were involved.

180. The available records do not explain how the change control process was circumvented when the defect in the [redacted] software was noted and resulted in the transfer of samples so that an adequate SOP could have been put in place.

DONOR SUITABILITY - Blood Pressure

181. During an FDA inspection of the Greater Chesapeake Region in April/June 2002, FDA noted that ARC failed to establish procedures that are adequate to ensure the safety of blood donors with low pre-donation blood pressure readings. BSD 51.110M, which established procedures for determining donor suitability, provided no normal lower blood pressure limit for allogeneic, directed, or apheresis donors. ARC accepted blood donations from donors with low pre-donation blood pressure and with no physician evaluation; and some of those donors experienced adverse reaction. In a written response to FDA dated 8/15/02, ARC explained the rationale for its pre-donation blood pressure policy, in part, by stating:

"In 1997, ARC performed a prospective study of 72,077 allogeneic whole blood donations in eight regions from

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6000 Metro Drive, Suite 101 **Baltimore, Maryland 21215**	FEI NUMBER: 1000123507
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED **TO: Ramesh Thadani, Executive Vice President and Chief Executive Officer**	
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random blood collection sites, seeking parameters relating to adverse donor reactions. Multivariate analysis revealed statistical associations between young age and female sex with an increase adverse reaction rate, but there was no statistical association between predonation systolic or diastolic blood pressure and adverse reactions."

However, during the current inspection of BHQ, when we asked to review this data and analysis for the 1997 study, we were provided with a two page undated, unsigned document titled "Study of Door Reaction" that indicates adverse reactions and donor pulse were being studied not donor blood pressure. In correspondence to FDA dated 10/23/02 from the ARC's Vice President, Quality Systems and Compliance Improvement, Biomedical Services, explained the discrepancy between the documentation and ARC's earlier statements to FDA as follows:

"The study was run in 1997 and we did not maintain the original analysis. However, we do have the initial database and we asked a contract statistician with whom we work frequently to repeat the data analysis on the original data."

Additionally, ARC's Senior Vice President, Quality and Regulatory Affairs, Biomedical Services, informed FDA in a letter dated 8/21/02, that ARC had "extensively studied adverse reactions." He referred to the studies described in the 8/15/02 correspondence, and stated that those studies "show no correlation between pre-donation blood pressure and adverse reactions." Despite the fact that ARC has no records showing blood pressure was included in the analysis, the Senior Vice President, Quality and Regulatory Affairs cited it as evidence that ARC's donor suitability screening procedure is adequate.

CONSENT DECREE CORRESPONDENCE:

182. In FDA's response to the 2001 ARC Annual report, FDA asked ARC to explain (Bates page 025328) the status of the "bug" that allows units to appear in the incorrect computer inventory location on the [redacted] and what interim steps ARC took to ensure it has control of inventory, pending a resolution of the problem (bug). ARC's response (Bates page 025543) states, "This potential bug was first reported in August 2001. After the submission of this information for the Annual Report, this bug report was further analyzed. A team of subject matter experts concluded that this is not a software problem (bug)." The record indicates the error had occurred because of a failure to complete the shipping transaction in NBCS not because of a bug in the system. During this inspection, we determined that the response to FDA (Bates page 025543) was inaccurate. This issue was, in fact, investigated as a "bug" ([redacted]), ARC has developed a SIP to identify and correct records system-wide, and drafted a BSL instructing the regions on handling the "bug" until corrected. As of 8/9/02, this BSL remained in draft.

RECORDS MANAGEMENT

183. BHQ did not always provide records requested by FDA during this inspection within two working days as required by BSD 14.101T "Record Management Policy for Blood Services." BHQ had significant delays in providing requested records.

184. The BSD for records management (BSD14.101T, pg. 4-6) indicates that "tracking records" must be retained indefinitely and facilities must list by information category all applicable records that are necessary to trace a unit of blood and its components from collection to final disposition. During this inspection, we requested these "lists" and none were

provided.

185. Deviation #2001-090-000205, dated 4/11/01, indicates QA/RA had not implemented BSD 14.101T, Records Management. The root cause analysis for the deviation was never completed, and there was no corrective or preventive action. On 7/6/02, during this inspection, the deviation report was changed to indicate Q&RA had fully implemented BSD 14.101T.

PRECHECK

186. BHQ failed to adequately investigate problems identified in the "precheck" system when the system identified ineligible donors as eligible.

A region submitted a potential system problem (PSP) on 3/9/99 noting two instances where a precheck device identified ineligible donors as eligible. BHQ never evaluated the PSP. The region resubmitted the PSP on 6/14/01, and it was assigned SP #590. On 7/20/01, the PSP was determined not to be a system problem and was closed without any investigation. There is no record to show that BHQ evaluated regional data to determine how many times ineligible donors were not identified by the "precheck" system and were allowed to donate. and were not identified by the "precheck" system. During an FDA inspection of the Greater Chesapeake and Potomac Region in April/June 2002, the FDA investigator noted that the precheck device identified an ineligible donor as eligible and, when the donor's social security number was entered eight subsequent times, the precheck device gave conflicting data on the eligibility of the donor.

PLASMA PRODUCT RETRIEVALS

BHQ failed to implement adequate procedures to ensure that complete product retrievals are performed when post donation information is received for Creutzfeldt-Jakob Disease (CJD) or new variant CJD, or that market withdrawals are performed for donors who test subsequently repeat reactive for HIV, HCV or HBV.

187. On 3/5/02, a region reported that it was trying to conduct a market withdrawal of a product from 10/26/00. The BSD 94.101T states that it is not necessary to perform a market withdrawal if the product is plasma for fractionation and is older than six months. Reportedly, all plasma for fractionation is pooled within six months of shipment. However, the region reported that its investigation found that the product remained in its warehouse. The region indicated that if plasma is over six months old and has not been shipped from the warehouse, the region is supposed to be informed. However, the region had not previously been informed that the plasma remained in the warehouse.

188. This problem was identified by the region on 3/5/02. BHQ did not provide to the regions a query of plasma products to be reviewed for recall or market withdrawal until 7/25/02, almost five months later.

189. The investigation does not indicate when BHQ initially became aware of this problem; however, the deviation report (2002-090-000076) indicates that some corrective action had already been taken in May 2001.

190. The corrective action does not require identifying plasma products erroneously released, prior to the change in procedure so that these products can be reported as BPDRs. BPDRs should be filed because ARC had the information

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION: 4/22 – 12/20/02
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indicating the product was unsuitable yet they released the product.

[redacted]

BHQ failed to maintain all records of an investigation into problems identified in the NBCS [redacted], which allow the labeling and release of previously manufactured blood components from donors testing HIV confirmed positive or HCV NAT confirmed positive. On 1/22/01, a region reported in [redacted] case #287445 a potential hazard when it received a complaint from a hospital that indicated the hospital had received a blood component for transfusion that was labeled "biohazardous." The investigation revealed that the assertions had been applied to the donor in error. However, the region indicated the "component status check" at the time of shipping with the Category [redacted] assertions was "passed." The region believed that the NBCS should have prevented the labeling and distribution of the component [redacted] case #287445 indicated that region BHQ QSS would review all [redacted] for NBCS and develop a query to determine if any other components with Category '[redacted]' assertions had been released.

191. BHQ had no record of this review of the [redacted]. During the inspection, a draft report dated 5/14/02 (approximately 16 months after the review was performed) was provided indicating that the [redacted] had been reviewed on 1/22-25/01. The [redacted] attached to the draft report are not dated. Therefore, there is no way to determine whether these records indicate how the [redacted] are set now or whether the [redacted] were set at the time of the BHQ review.

192. The draft report indicates that one rule for the [redacted] would be that "No component from any donor with [redacted] class assertion will be released no matter when collected except for autologous and exceptional release." According to the Vice President, Quality Assurance, Blood and Plasma Operations, the BHQ group responsible for review of the [redacted] did recommend that this rule should be adopted yet senior management did not accept the recommendation. There is no record of who made this decision, when the decision was made, or on what basis the decision was made.

193. BHQ provided no information to the user regions that NOT all products which pass the component status check are acceptable for release and that products that pass [redacted] may not be suitable for release due to the [redacted] problem identified 1/22/01.

194. A memo dated 2/2/01 to the ARC's Executive Directors states that BHQ sent results of an unvalidated query to all regions that identified potential erroneously released products from donors while in an [redacted] class assertion. There are no record of the query results or evidence showing which query was run. A memo to the file dated 4/25/02 (14 months later) is identified as a summary of findings of SIP [redacted]. This record indicates SIP [redacted] was developed to identify any non-autologous components shipped from a donor with an '[redacted]' class assertion. This memo indicates that 13 components were recalled as a result of the query and they were recalled because of duplicate records that were not completely investigated at the time of discovery. There is no record of follow up to determine why regions were not adequately investigating the duplicate records at the time of discovery and recalling components when appropriate. There is no record of any additional investigation to determine if products associated with other deferral categories were released when regions were not adequately investigating duplicate records.

195. The record provided does not include evidence that a validated query was completed, that the results were reviewed, or that the query used, SIP [redacted], would identify the desired correct records. The case notes for [redacted] case #287445, dated 2/23/01, indicates SIP [redacted] was not directly related to this case and the notes regarding development of this query should not be in this case. There is no documentation of a resolution of this problem in [redacted] case #287445 or #290892.

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FAILURE TO COMPLETE CORRECTIVE ACTION:

QA did not ensure all corrective action developed in response to the FDA's February-April 200 inspection were completed and effective.

196. A review/audit of the corrective action promised to FDA was performed in February/March 2001. As a result, 28 deviation reports were written citing the failure to properly address the FDA 483 observations. For example, the QRA audit noted that ARC had committed to a QA review of the Donor File Check process and this was not occurring. The response indicates the root cause as "Decision was made by senior management to have a moratorium on BHQ audits due to BHQ restructure." QA did not ensure a critical review step was being performed.

197. On 11/9/2000, the Supplier Quality Branch of QRA performed an independent review of the FDA 483 response and noted that in many cases the root cause analysis was missing or incorrect and that measurable effective monitoring criteria were not defined.

198. Deviation #2001-090-000182 noted that QRA identified a need to and a failure to trend [redacted] cases. We noted during this inspection that BHQ is still not trending [redacted] cases.

199. A task force report dated 3/29/01 noted that root cause analysis had not been performed, as required by BSD, for the corrective action plans provided to FDA, which would have addressed the problems found during FDA's February-April 2000 inspection. The task force determined that root cause analysis was not completed nine months after the original corrective action was developed and submitted to FDA.

200. BSD 92.103T, Deviations, Version 1.1., April 2001, is inadequate because it does not require an investigation to be performed to determine the root cause and to even implement a preventive action for deviations classified as "log, correct and trend" (LCT). Our review of the deviations associated with inventory reconciliation problems revealed that regions were classifying the failure to perform inventory reconciliation of quarantine locations as LCTs, which are not required to be investigated. For example: the Alabama Region did not perform daily inventory reconciliation on the quarantine locations identified as A-BIOQ and A-QUAR on 7/27/2001; 7/29/2001; 8/4/2001, 8/5/2001, 8/11/2001, 8/12/2001, 8/18/2001, 8/19/2001, 8/21/2001 and 8/26/2001 as reported in LCT #2001041001228. Because this deviation was classified as LCT, the root cause was not investigated and no preventive action was developed.

INTERNAL AUDITS:

201. BHQ has an inadequate system in place to track outside and internal audits. During the inspection, we requested copies of all special audits performed. BHQ was unable to determine the types of audits performed, whether corrective actions had been completed, and in which facilities audits were performed.

An outside auditor conducted an audit of the Southern Region in August 2000. A draft report dated 9/8/00 from this audit was provided during this inspection; the final report was not available. The report lists 24 observations which the summary indicates represent "significant product quality risks..."

202. BHQ has no record of any follow-up to the audit of the Southern Region until June 2002 when FDA

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requested records during the current inspection.

203. The assessment conducted by BHQ during this inspection lists four of nine observations with the target date for corrective action as TBD, "to be determined," despite the auditors' judgement that they represent "significant product quality risks..."

204. The 6/28/02 and 6/27/02 assessment provided during this inspection includes no record of the effectiveness of any of the corrective actions reportedly implemented.

[redacted] conducted an audit on 6/12-13/00 of the current software development methodology for ARC.

205. There was no record of any follow up of the audit findings until requested by FDA during the current inspection.

206. The undated, unsigned assessment of the [redacted] audit results completed during this inspection indicates all five observations listed are closed and two of the five observations will not be completed. There is no indication QA reviewed and approved this plan.

An internal audit was conducted April/May 2000 of the [redacted] supports the NBCS.

207. There were no records of any follow up of the audit findings until after FDA requested records during the current inspection.

208. The undated, unsigned assessment completed during the inspection only addresses 23 of 33 observations. There is no record of the effectiveness of these corrective actions.

Several audits were performed in the Salt Lake City Region following the FDA inspection of that region in March/May 2001.

209. There was no record of the assessments of the audit findings following the 5/23/02 and 7/26/02 audits until August 12, 2002 when FDA requested themduring this inspection.

210. Following the FDA inspection of BHQ in February-April 2000, a review of all BSDs and package inserts was performed for all testing performed by the NTLs to determine if any additional discrepancies were noted. This review did not identify any discrepancies noted for antibody testing; however, the review of the NTL procedure provided for an automated method and the product insert for the reagent cells do not indicate automated methods are appropriate.

ADVERSE DONOR REACTIONS:

211. Prior to May, 2002, procedures for the Investigation, Management, and Reporting of Adverse Reactions and Experiences did not require regions to submit copies of all adverse donor reaction reports and investigations to BHQ as required in Paragraph III.B.17.a of the May 12, 1993 Consent Decree. The procedures prior to May 2002 only required the regions to submit to the Medical Office/BHQ copies of adverse reaction reports, if the adverse reaction resulted in hospitalization or fatality of the donor.

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212. Procedures for the Investigation, Management, and Reporting of Adverse Reactions and Experiences require a final report of the donor adverse reaction to be sent to the Medical Office/BHQ, within 30 calendar days of the adverse event. Of the 30 reports reviewed during this inspection for the time period of January, 2002 to July 17, 2002, the following six reports were not submitted to the Medical Office/BHQ, within 30 calendar days of the event:

ARC Log Number	*ARC Region*	*Date event occurred*	*Date BHQ Medical Office received report*	*Description of Adverse Event*
[redacted]	New England	09/15/01	01/03/02 **3 ½ months post event**	Donor reported having a post-donation seizure
[redacted]	New York/Penn	10/19/01	01/28/02 **3 months post event**	Donor was hospitalized due to prolonged post-donation recovery
[redacted]	Indiana/Ohio	07/25/01	02/19/02 **6 ½ months post event**	Donor lost consciousness post-donation, fell and broke ankle
[redacted]	North Central	07/18/01	03/25/02 **8 months post event**	Post-donation loss of consciousness resulting in hospitalization
[redacted]	Penn/Jersey	10/18/01	04/19/02 **3 months post event**	Post-donation loss of consciousness resulting in hospitalization
[redacted]	North Central	02/18/02	04/26/02 **2 months post event**	Post-donation loss of consciousness resulting in hospitalization

213. Procedures for the Investigation, Management, and Reporting of Adverse Reactions reported to the Medical Officer at BHQ, do not specify timeframes for review of these reports by the Medical Officer to ensure that each region has properly investigated the cause of the adverse reaction, to determine if the event was the result of a system defect, and

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to ensure that corrective action was taken promptly, as required in Paragraph III.B.17b of the May 13, 1992 Consent Decree. Of the thirty reports reviewed during this inspection for the time period of January, 2002 to July 17, 2002, the review of at least four reports by the Medical Officer was not done for at least 2 weeks following receipt of the report ([redacted]).

lam 12/20/02

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Linda J. Carter Investigator Brenda S. Hattersley, Investigator Stephanie Hardy, Investigator	Linda J. Carter, Investigator Brenda S. Hattersley, Investigator	12/20/02