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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION 9/2/10 – 10/29/10
6000 Metro Drive, Suite 101 Baltimore, MD 21215 Phone: 410-779-5455	FEI NUMBER To Be Determined
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Janis F. Lugo, MBA, MT (ASCP) SBB, Executive Director	
FIRM NAME American Red Cross Donor and Client Support Center	STREET ADDRESS 700 Spring Garden Street
CITY, STATE AND ZIP CODE Philadelphia, PA 19123	TYPE OF ESTABLISHMENT INSPECTED Donor and Client Management Establishment

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DURING AN INSPECTION OF YOUR FIRM, WE OBSERVED:

Management Control:

1. Oversight of Donor Management Consolidation: ARC has consolidated the donor management activities that were previously performed in 35 of their 36 regional offices (the Puerto Rico Region will be merged after BioArch is implemented) into the newly created Donor Client Support Center (DCSC). The DCSC is located in two facilities, one in Charlotte, North Carolina, and one at this location in Philadelphia, Pennsylvania. The consolidation began in May 2008 with the Carolinas Region and the Penn-Jersey Region. The other regions were routinely consolidated until the project was completed in March 2010.

The donor management activities now being performed by the DCSC include, but are not limited to, the following:

- Donor care and qualification functions that include answering eligibility questions from the donors; donor deferrals; post donation and call back activities, donor complications and complaints; receipt of test results and entry of the results into the NBCS software; management of follow up testing with the donor; donor reentry/reinstatement; deferral and surveillance management; managing donor requests for test results and blood types; donor notification of reactive test results and donor counseling; and military, state and health department notifications.

- Client support services that include the management of blood product retrievals; consignee notification for the release of unsuitable blood components; case investigations for possible transfusion transmitted infections, adverse reactions and bacterial contaminations; lookbacks; and serves as the liaison for regional/divisional medical directors.

- Data management functions include the management of the National Donor Deferral Registry and the Donor File Check process.

- Problem management tasks for the Philadelphia DCSC are performed in Philadelphia as well as in the Charlotte DCSC, that include the detection, investigation, evaluation, correction, and monitoring of all problems, trends and system problems.

However, during the process of consolidating donor management functions into the DCSC, ARC has failed to comply with Paragraph IV of the Amended Consent Decree of Permanent Injunction entered on April 15, 2003 (hereafter, referred to as the Decree), in that ARC has failed to "...establish, implement and continuously maintain adequate methods, facilities, systems, and controls to ensure that ARC does not collect, manufacture, process, pack, hold, or distribute any article of drug...that is adulterated...; misbranded...; or otherwise in violation of the FD&C Act, the PHS Act, and regulations promulgated thereunder, including but not limited to, 21 C.F.R. Parts 210-211 and Parts 600-680...."

During the consolidation of the regional facilities into the DCSC from May 2008 through March 2010, internal audits and a Problem Management/Quality Assurance assessment were performed at the two DCSC facilities. The findings and the

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	Nancy L. Rosa Linda D. Matthews	Nancy L. Rosa, CO Linda S. Matthews, Investigator	10/29/10

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subsequent investigations indicated that the DCSC was chronically understaffed and lacked process controls to ensure timely and adequate performance of the donor management functions. The DCSC repeatedly promised corrective actions, some of which have yet to be completed or have not been effective.
During the consolidation phase, ARC had periodic senior management meetings, Quality and Compliance Oversight Committee (QCOC) meetings, Board of Governors' meetings in which the DCSC consolidation project was discussed. Quarterly and annual quality assurance and training reports were being submitted to ARC's senior management, as well. The meeting minutes indicate that ARC management was aware of the audit findings and the staffing and proficiency issues, and that the QCOC was monitoring the situation to determine whether the consolidation should continue as scheduled.

Once the consolidation was completed in March 2010, the minutes indicate that ARC management had concerns about the DCSC performance and that it continued to be understaffed and had a backlog of approximately 18,000 donor management cases that had not been process verified as required in Work Instruction 11.3.028, Process Verification, Version 1.1.

In addition, there were other indications to ARC senior management that the DCSC had quality assurance and problem management staffing problems. For example: a DCSC FTE (Full Time Employee) staffing document was submitted by the DCSC in July and September 2009 indicating that "the organization is currently operating under the façade that the DCSC is self supportive in its QA and PM functions....this can immediately cause the DCSC to become unsustainable and fall into a backlog...another large concern is that every five weeks additional regions continue to transfer to the DCSC. Therefore, the situation is escalating to a point where the field will not be able to support the volume." Yet, ARC management allowed the consolidation to continue.

After completion of the consolidation in March 2010, internal audits, assessment reports, and meeting minutes indicate that the DCSC continued to have problems with adequate staffing, proficiency, and timely and effective management of donor management cases and of problems. For example,

A. In April 2010, the Biomedical Headquarters (BHQ)/QCOC meeting minutes indicate that the DCSC had a backlog of approximately 18,000 donor management cases that had not been process verified as required in Work Instruction 11.3.028, Process Verification, Version 1.1.

B. The April 2010 audit report states that the DCSC root cause of the repeat observation pertaining to timely problem management is "The DCSC Problem Management Department does not have the resources to consistently manage problems in a timely manner."

C. The May 2010, DCSC staffing report indicates that "...without additional staff dedicated to answering eligibility calls, the DCSS position would be understaffed. This understaffing could create a situation of a continually growing backlog, overtime pay required, and a decreased ability to handle natural spikes in incoming work."

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D. In July 2010, senior management placed the DCSC on a Compliance Improvement Strategy (CIS) because it was determined to be a "high compliance risk" based on internal audits and FDA 483s received since March 2009.

Yet, the CIS was not finalized until 9/29/10 after this inspection was initiated. The final plan states "Numbers and proficiency of staff are not adequate to effectively execute assigned tasks and responsibilities in a compliant manner; inadequate supervision and oversight." The plan further states "in each of the functional areas where there is a back-log of work identified that will be included in the back-log plan for managing open cases. The Back-log Plan will provide the details of how any back-log will be managed and monitored, including defined commitments for reducing the back-log while appropriately managing new cases." (As noted above, there was an approximate 18,000 case backlog that was discussed in April 2010. As of the beginning of this inspection the backlog in Charlotte was 11,531 open cases (and 4949 Donor Reaction/Injury Reports [DRIR]) and in Philadelphia it was 3,552 open cases (and 306 DRIRs).

2. Quality Assurance (QA) at the DCSC: ARC has failed to follow Paragraph IV.A.2.a. of the Decree which requires that the "director of quality assurance shall be responsible for all ARC Biomedical Services quality assurance functions including, but not limited to, ensuring the establishment, implementation, and continuous maintenance of comprehensive QA/QC programs..." The DCSC QA program is not ensuring all donor management operations are being performed effectively at the Philadelphia DCSC.

A. At the outset of this inspection, there was a backlog of open cases that are required to be reviewed.

i. Donor Status Change Records, Component Status Change Records, and Component Information Forms are required to have process verification prior to closure of a case, as required in Work Instruction 11.3.028, Process Verification, Version 1.1. A backlog of 3,552 cases, dating as far back as July 2009, existed at the Philadelphia DCSC facility.

ii. DRIRs require a Medical Director review and a final quality review. A backlog of 306 open DRIRs, dating as far back as August 2009, existed at the Philadelphia DCSC facility.

B. There have been no Quality Process Reviews performed by the QA staff since the Philadelphia DCSC was created in 2008. Quality Process Reviews are required in Directive, 02.2.012, Quality Process Reviews, Version 2.1, and are to be conducted by the QA staff on an ongoing basis to review the systems and processes being performed by the operations staff at the DCSC. In addition, these reviews are to "identify process improvement opportunities, possible procedure or compliance violations, and confirmation of processes operating in a state of control."

C. ARC has failed to develop a Facility Quality Plan (FQP) for the DCSC as required in Directive 02.2.011, Process for Developing a Facility Quality Plan, Version 1.1. The FQP "ensures that each facility project ... meets current Good Manufacturing Practices (cGMP) regulations, as applicable."

D. The Quarterly QA reports, required in Paragraph IV.A.b. of the Decree, are required to be submitted

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"...in writing to ARC senior management and ARC Biomedical Services senior management..." and did not portray the seriousness of the staffing and proficiency problems occurring in the DCSC.

There were eight Quarterly QA reports submitted to ARC senior management and ARC Biomedical Services senior management beginning in April 2008 through March 2010, and it was not until the October-December 2009 report that the "capacity for problem management" and the backlog of open problems was included in the Quarterly Quality Assurance Report. In fact, there continued to be very little mention of the serious problems occurring in the DCSC in the subsequent report for the January-March 2010 quarterly report.

E. A QA Assessment was performed in October 2009 and a PM Assessment was performed in November 2009. Yet, the reports for these assessments were not issued until April 2010. The reports identified staffing and workload issues due to the continuous transitioning; the QA staff in Philadelphia has no donor management experience; the QA staff was on board for six months and was not fully trained; staff was struggling and there was no support from management; inadequate change management; and planning was not adequate.

3. BHQ Audits of the DCSC: Although multiple Board of Governors Committee meeting notes state that Quality Assurance (through the Quality Compliance Oversight Committee) was closely monitoring all corrective actions related to BHQ audit observations and ensuring that staffing levels were adequate to continue merging the regions' donor management functions into the DCSC, a review of numerous problems opened as a result of the audits found that corrective actions were not developed and/or implemented promptly. However, the merging of regions with the DCSC continued. For example,

A. Problem Management Audit Observations/Findings

NOTE: Different problem management functions are performed at the two DCSC facilities; therefore, BHQ audit observations and corrective actions affected both locations. For example, one audit report states that all level 2/3 problems were being managed in Charlotte because Philadelphia was not fully staffed. QA management also stated that all PDI problems are managed by staff in Philadelphia.

i. The October 2008 BHQ audit of the Philadelphia DCSC facility cited the untimely management of problems. The DCSC opened E-0455175, I-0017862-FC (discovered 10/22/08 and closed on 3/31/10) and determined root causes that included inadequate staffing levels, inexperienced staff, training, and a lack of tracking mechanisms to ensure timely problem management. The corrective action plan (CAP) described included hiring and training additional staff, developing tracking queries for the DCSC, and establishing a group to manage PDI (post donation information) problems. QA approved CAP on 2/3/10 and implementation is documented as having been completed on 2/4/10 and 3/23/10. I-0017862-FC states that the effective check (EC) would be performed under E-0680169, I-0017441-FC.

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ii. The March 2009 BHQ audit of the Charlotte DCSC facility cited untimely management of problems. There was a backlog of 200 problems. The DCSC opened E-0551794, I-0013588-FC (discovered 3/27/09, closed 5/4/10) and determined that root causes included inadequate staffing, only two staff experienced with level 2/3 problems, and lack of oversight. The CAP described included train staff to handle level 2/3 problems, assign oversight responsibilities, and track aging problems. QA approved the CAP on 4/29/09. I-0013588-FC documented the CAP was implemented between 4/30/09 and 7/30/09. The sustained EC was completed on 4/16/10 and the CAP was deemed effective.

iii. The June 2009 BHQ audit of the Philadelphia DCSC facility cited untimely management of problems. (The audit report indicated that staff had been hired and that all level 2/3 problems were being managed in Charlotte because Philadelphia was not fully staffed. The DCSC continued to have a backlog of problems.) The DCSC opened E-0595168, I-0015324-FC (discovered 6/5/09, still opened as of 10/8/10) and determined that root causes included inadequate monitoring processes, staffing proficiency, and workload. QA approved the CAP on 8/24/09 after two CAP extensions. The CAP was implemented on 10/26/09, 11/12/09, and 2/24/10. The final EC had not been completed as of 10/11/10.

iv. The October 2009 BHQ audit of the Charlotte DCSC facility cited untimely management of problems. The DCSC opened E-0680169, I-0017441-FC (discovered 10/23/09, closed 6/1/10) and documented the root cause as lack of a good tracking mechanism, problems were not always assigned as discovered, and the outsourcing of PM cases due to staffing levels. The described CAP included developing tracking mechanisms and hiring QA/PM staff by 12/1/09. QA approved the CAP on 11/30/09. One tracking mechanism was implemented on 10/26/09, another was implemented on 1/29/10, and vacancies were opened on 1/29/10. The EC was completed on 5/3/10 and the problem closed 6/1/10.

v. The January 2010 BHQ audit of the Charlotte DCSC facility cited untimely management of problems. The DCSC response referred to previously developed CAPs documented in I-0017862-FC (the CAP for the October 2008 audit) and I-0017441-FC (the CAP for the October 2009 audit). Both of these issues were still open at the time of the January 2010 audit. The root cause cited in the DCSC response to the audit was, "The DCSC Problem Management Department does not have the resources to consistently manage problems in a timely manner."

vi. The January 2010 BHQ audit of the Philadelphia DCSC facility cited untimely management of problems. The DCSC response referred to previously developed CAPs documented in I-0017862-FC (the CAP for the October 2008 audit) and I-0017441-FC (the CAP for the October 2009 audit). The root causes described in the DCSC response was a lack of resources to consistently manage problems in a timely manner. The CAP included hiring staff, including a PM manager, and establishing a separate PDI problem group.

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B. In addition to PM observations, the June 2009 BHQ audit of the Philadelphia DCSC facility cited observations pertaining to failure to review donor management records in a timely manner. Specifically,

i. PDI and donor call back cases were not being process verified in "a reasonable time period." The DCSC opened E-0595192, I-0020482-FC (discovered 6/5/09, still open as of 10/8/10, I-0020482-FC was opened on 6/11/10) and determined the root cause to include process verification was not considered a priority because there is no deadline, staff proficiency, and competing priorities. The audit response states that the DCSC was already aware of the process verification backlog and had developed a plan to address it. The CAP included slowing down the consolidation and changing the work flow. The proposed EC states that the QCOC and QA would do periodic case reviews to ensure that process verification is timely and that cases are completed. QA approved the CAP on 7/20/10. Only one part of the CAP is documented as having been completed on 8/30/10. The Exception Report states that an EC failed, but there is no documentation of any follow-up.

ii. The DCSC failed to ensure timely and accurate management of DRIRs. The DCSC opened E-0595184, I-0011152-NF, I-0020136-FC (discovered 6/5/09, closed 8/3/10). (The problem was also linked to E-079874, I-0010881-FC which addresses the FDA 483 observation on 4/23/10.) The DCSC determined the root cause to include lack of staff proficiency and lack of a well defined process. The DCSC response stated that it was aware of the problem and had held workshops and proposed to establish a DRIR group by 8/1/09 and conduct another workshop. Additionally, the CAP included time studies by a lean engineer, developing a backlog plan, clarifying DRIR time frames, and hirin[b(4)] staff for donor eligibility calls. QA approved the CAP on 6/2/10. The Issue indicates the CAP was implemented on 5/24/10, 6/1/10, and 7/21/10. No due date has been documented for ECs and they have not been completed as of 9/2/10.

Problem Management -- Donor Reaction/Injury Reports (DRIRs):

4. ARC has identified trends related to DRIRs beginning in 6/09, but has failed to promptly and thoroughly correct and prevent recurrence of DRIR documentation problems.

BC-40-01-02—Adverse reaction donor: incorrect/missing documentation on Donor Reaction/Injury Reports:

A. Trend condition 4 was met at the DCSC in 6/09, discovered 9/30/09 (when the DCSC began trending), and E-0664347 was created. The root cause investigation and CAP development began on 2/4/10. An extension of the 30 day CAP development time frame was requested 1/14/10 and 2/5/10 and granted on 2/8/10, four months after discovery of the trend problem. The documented justification for the extension was that the original CAP was due on 10/30/09, but the problem was not assigned to the Problem Investigator until 1/12/10.

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E-0664347 and the related Issue, I-0018632-FC, states that the root cause for the problem is "staff are hurried and rushing to complete the form and overlook errors and omission. The DRIR is filled out electronically and it is easy to overlook omissions on the form." The Issue further states that "no additional corrective actions are necessary at this time," and refers to corrective actions implemented on 11/24/09 and 1/31/09 under BHQ system trend E-0603257. QA approved the proposed CAP (no additional corrective actions) on 2/18/10 and the exception was closed 2/24/10.

B. BHQ System Trend E-0603257 was discovered on 6/23/09 and closed 6/29/10. The described problem is incomplete or incorrect documentation of DRIRs. The root causes cited on I-0000334-FC include "donor adverse reactions are rare stressful events and staff busy attending to the donor fail to document all required information...," "staff inattention to detail and lack of focus..., misinterpretation of the Work Instructions, failure to refer to the form instructions, and gaps in DRIR instructions, and the format of the DRIR form. The CAP was approved by QA on 12/2/09, approximately five months after discovery of the trend. The CAP included the release of a communication to remind staff of requirements and clarify instructions in 11/09. The EC success criterion was (b)(4)% improvement. On 6/15/10, the EC used data from 2/1/10 through 4/30/10, and was deemed effective with only a 41% improvement.

C. Trend condition 4 was met again at the DCSC in 4/10, discovered 5/25/10, and E-0811555 was created. The root causes cited in I-0020944-FC include staff not reviewing their work and "shortage of dedicated DRIR staff." An extension for CAP development was requested on 7/13/10 and granted on 7/14/10 because the Problem Investigator was working on training and a trend problem with another employee. The CAP, which was approved by QA on 9/8/10, is to remind staff of requirements in a face-to-face communication with affected staff, to hire additional DRIR staff and to offer refresher training to other staff performing DRIR tasks. The staff reminders are documented as completed on 9/27/10, four months after discovery of the trend. The problem was still open as of 10/1/10.

5. On 7/9/10, ARC discovered a problem related to receipt of DRIRs at the DCSC from the regions, but an investigation into the root cause has not been completed and development of a CAP has been postponed until 11/12/10. Specifically, a review of closed DRIRs identified four cases that included a statement on the DRIR that the donor disposition was "unable to determine, no DRIR available from the collection site." Additionally, the records contained two e-mails sent from the DCSC to a Regional Medical Director, both dated 8/9/10. The DCSC explained that ARC Hemovigilance Program discovered on 7/9/10 that DRIRs with an X complication code in NBCS were missing from the DCSC (b) (4) program. The DCSC opened Exception E-0836426. As of 10/8/10, the DCSC had not investigated the specific root cause of missing DRIRs. (ARC's record review, completed in 7/10, for the period 12/1/09 through 6/30/10 identified 292 cases with missing DRIRs. Of those cases, the failure mode for 167 was unknown.) The minutes from multiple meetings that occurred in 9/10 are attached to the exception but do not include discussion of the root cause of this specific described problem. QA approved two CAP extensions. The current CAP due date is 11/12/10.

6. On 9/29/10, a review of 13 randomly selected DRIR case files opened in the DCSC in 1/10, 2/10, and 3/10, but not yet processed verified, found six with no final quality review and six with no Medical Director review, as required by Form: Donor Reaction and Injury Record, 15.4.frm015, v-1.2. Specifically,

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A. The following cases had no final quality review or an untimely final quality review:

P201003221135o08, opened 3/22/10
P201002251434o19, opened 2/25/10
P201002261722o19, opened 2/25/10
P201001061919o72, opened 1/6/10
P201002260816o32, opened 2/26/10
P20100120019-P56 was opened on 1/20/10, but had no final quality review until 9/22/10.

B. The following cases had an untimely Medical Director review or no Medical Director review:

P201002010936o28 was opened 2/1/10, but not reviewed until 7/29/10
P201001101700o31 was opened 1/10/10, but not reviewed until 5/12/10
P201001252057o75 was opened 1/25/10, but not reviewed until 9/23/10
P201002101357o8d was opened 2/10/10, but not reviewed until 4/6/10
P201002231258o37 was opened 2/23/10, but not reviewed as of the date of this inspection
P201002051004o46 was opened 2/5/10, but not reviewed as of the date of this inspection

C. Although, in response to other recent FDA 483s, ARC has taken steps to establish a time frame for completion of the final quality review, there is still no time frame for completion of the Medical Director review.

Problem Management – Management of Suspect Blood Products:

7. ARC has identified trends related to management of suspect blood products and inventory management, but has failed to promptly and thoroughly correct the problems. For example,

QC-96-01-25—product in wrong physical location, wrong electronic location:

A. Trend condition 4 was met at the DCSC in 10/09, discovered on 11/30/09, and E-0707671 was created. The problem was closed 2/18/10. The documented root cause is "Current process flows and functional roles do not meet System 11 requirements as they include hand-offs with steps that should be performed consecutively and immediately." Issue, I-0018721-FC, states that no formal corrective action will be taken due the corrective actions implemented under another Exception Report. QA approved the CAP on 2/16/10.

B. Trend condition 2 was met at the DCSC in 2/10, discovered on 3/24/10, and E-0774042 was created. As of 10/1/10, the problem was still open. The documented root cause is "Due to the original design of the Donor and Client Support Center (DCSC) workflow, there is a waiting period from when unsuitable components are identified to when they are managed/retrieved." Issue, I-0019647-FC, indicates that QA approved the CAP on 5/27/10 and it was implemented on the same day. The only description of the CAP is a reference to corrective actions in I-0019389-FC which was for BPD code 90-01-05 [failure to adequately manage potentially non-conforming products (product not released)], but has the

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Janis F. Lugo, MBA, MT (ASCP) SBB, Executive Director	
FIRM NAME American Red Cross Donor and Client Support Center	STREET ADDRESS 700 Spring Garden Street
CITY, STATE AND ZIP CODE Philadelphia, PA 19123	TYPE OF ESTABLISHMENT INSPECTED Donor and Client Management Establishment

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same documented root cause. The interim EC for E-0774042, I-0019647-FC was deemed effective on 7/27/10 and the sustained EC, which was due 8/26/10, was not documented as completed as of 10/1/10. However, I-0019389-FC indicates that implementation of the four-part CAP was not completed in full until 10/5/10; approximately one year after the 10/09 trend was identified with the same root cause, the original work flow design.

QC-90-01-05-- failure to adequately manage potentially non-conforming products (product not released):

C. Trend condition 5 was met at the DCSC in 5/10, discovered on 6/30/10, and E-0831104 was created. The problem was closed on 8/2/10. The associated Issue, I-0011219-NF cites the root cause as "The original process flows associated with these gain control and retrieval processes did not provide staff with the experience and responsibility to perform their required functions as a suspect product identifier." It refers to corrective actions taken under I-0020891-FC, I-0016426-FC, I-0019143-FC, and I-0019389-FC. A review of E-0625538 (discovered 7/31/09) and E-0780785 (discovered 3/31/10), which are both associated with I-0019389-FC, found that a CAP extension was approved for both problems on 4/30/10. Multiple CAP extensions were previously approved for E-0625538. QA approved the CAP on 5/19/10. One part of the CAP was implemented by 5/31/10, but the other three parts were not implemented until 10/5/10. Both problems remained open as of 10/14/10—one for more than 15 months and one for more than six months

Problem Management - Confirmatory Test Results and the DDR:

8. ARC has identified trends related to management of confirmatory test results and DDR entry, but has failed to promptly and thoroughly investigate, correct, and prevent the problems. For example,

DD-30-01-10—confirmatory results/DDR entry not performed / not entered timely:

A. Trend condition 4 was met in the DCSC in 9/09, discovered on 10/29/09, and E-0683307 (level 2) was created. The problem was closed on 2/23/10. The associated Issue, I-0017599, cites the root causes as inattention to detail due to staff being new, not understanding, or rushing. The proposed CAP states "See below for corrective actions "being taken in I-0016921-FC address these issues." QA approved the CAP on 12/18/09. The CAP implemented on 12/18/09 is described in the Issue as "Reiterate the need for staff to slow down and pay closer attention to information being entered and to make sure that they go back and review entries prior to moving to the next step." Additionally, the CAP included supervisors/designees observing involved staff while performing test result entry. The EC was performed and the corrective action was deemed effective on 2/19/2010. However, the Issue, I-0016921-FC, referenced as the CAP for the trend problem indicates that the CAP was implemented and that the ECs had not been completed before the trend problem was closed. Specifically, the observation by supervisors/designees is documented as having been completed on 2/3/10, not 12/18/09.

Review of I-0016921-FC revealed that QA approved the CAP on 12/23/09. The CAP consisted of supervisor/designee observation, reiterating the need to "slow down' and "pay closer attention," and clarifying when a specific form was necessary. Those CAPs were implemented 2/3/10, 2/3/10, and 4/27/10, respectively. The EC was completed 6/23/10.

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The corrective actions were deemed effective and all of the associated problems were closed on 6/24/10.

DD-30-01-12--incorrect/no computer property/assertion applied (no product released:

B. A trend for DD-30-01-12 was identified on 10/29/09 for 9/09. The root cause also cites misinterpretation of instructions, staff new to task, staff not aware they could remove assertions, limited experience with holds. The investigation does not address why staff have been are released to perform tasks they do not understand. The DCSC had a recurrence of DD-30-01-12 in 8/10.

9. ARC has identified trends related to consignee notification, but has failed to promptly and thoroughly correct and prevent the problems. For example,

MI-00-01-19—48 hour notification to consignee not performed/complete/timely for distributed expired products & MI-00-01-23—recall/market withdrawal records incorrect/incomplete/not timely (also includes late follow up letters to consignees):

A. Trend condition 4 was met for BPD code MI-00-01-09 in 6/09, discovered on 9/30/09, and E-0664458 was created on 9/30/09. CAP development extensions were approved on 10/20/09 and on 4/16/10. The justification for the 4/16/10 extension was "...staff issues and lack of good tracking mechanisms..." No investigation was documented until 5/18/10. QA approved the CAP on 7/6/10, 10 months after discovery of the trend.

I-0020096-FC, cites the root causes as "poor work practices/work flow including poor follow-up, insufficient reviews, and oversight." The described CAP is to restructure the DCSC into functional teams and to revise work flows to standardize gain control activities. Approximately one year after discovery of the trend, the CAP has not been fully implemented. Functionalization was implemented at the Philadelphia site in 6/10 and at the Charlotte cite in 9/10, but not documented in I-0020096-FC as of 10/1/10. The status of the work flow revisions in not documented. The trend problem remained open as of 10/1/10.

B. On 9/24/10, the DCSC discovered that in 8/10, it met trend condition 4 for MI-00-01-23 and created E-0878847. The problem description refers to the 6/09 MI-00-01-09 trend being managed under E-0664458.

Significant Corrective Action Report (SCA) – Health Department Notifications of Confirmed Positive Infectious Disease Markers:

10. An SCA Report was submitted to the FDA on 7/22/10 as required in Paragraph XIX of the Amended Consent Decree. This SCA pertains to the notification to health departments when a donor has been determined to be confirmed positive for infectious disease markers, such as HIV, Hepatitis B, Hepatitis C, West Nile Virus and syphilis, as required in ARC's Directive 14.2.008, Managing Test Results, Donor Notification, and Counseling, Version 1.2. ARC's failure to notify health departments was initially identified during an FDA inspection from 5/24/10 to 6/4/10.

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An Exception Report (E-0822345) and Issue (I-0011107-NF), created on 7/6/10 and referenced in the 7/22/10 SCA with no formal corrective action planned, required that a retrospective review of cases in which health department notifications were required to be made be completed by 7/30/10, including performing any follow up health notifications when discovered that notification had never been performed.

Because there was no formal corrective action plan developed for this SCA and there was no follow up or monitoring of this review performed at the DCSC, it was not until the status of the retrospective review was requested on 9/22/10 by the FDA that it was discovered all health department notifications had not been made and some health departments were not notified for months after confirmed positive disease markers were received.

Management of the National Donor Deferral Registry (NDDR) and Problem Management Associated with the NDDR:

11. The NDDR has been managed by the Philadelphia DCSC since the merger of the regions into the DCSCs in March 22, 2010, except for the Puerto Rico Region which was merged on May 31, 2010. However, the DCSC does not have written procedures specific to the Philadelphia DCSC's management of the NDDR and the Donor File Check process since the transfer of these processes to the DCSC. This facility continues to utilize the written procedures that were in place when the NDDR was managed at BHQ and the Donor File Checks were managed in each regional facility.

12. The Philadelphia DCSC has failed to follow ARC's Problem Management SOPs in that the problems associated the proper deferral of donors in the NDDR are not thoroughly investigated. For example,

A. Problem Report E-0808208 and Issue I-0020419-FC, occurred 4/25/10 and discovered 5/17/10: The problem description indicates that HIV confirmatory test results were received at the DCSC on 4/25/10 but a Category X assertion was not added to the donor record that would place the donor in the NDDR when the next (b) (4) DDR Out cycle was going to be performed by the Philadelphia DCSC on 5/7/10. Therefore, a Donor File Check was required to be performed. A Level 3 investigation was performed but did not include a reason why it took 22 days from the date the DCSC received the test results on 4/25/10 to discover that the donor was not placed in the NDDR during the next DDR Out cycle on 5/7/10. In addition, the investigation did not include why it took nine days for staff notification to occur. This problem has yet to be closed.

B. Problem Report E-0808186/I-0020550-FC, occurred 5/2/10 and discovered 5/17/10: The problem description indicates that HBsAg test results received at the DCSC were not entered into the NDDR timely causing a Donor File Check to be performed for two donors (Whole Blood #b(6) . A Level 3 investigation was performed but did not include a reason why it took 15 days to discover that the donors were not placed in the NDDR correctly by the DCSC. In addition, the investigation did not address why infectious disease test results are being sent to the DCSC in various formats with no DCSC written procedure in place that addresses the various formats that must be monitored by the staff. The investigation also did not include why it took nine days for staff notification to occur. This problem has yet to be closed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Linda S. Matthingly	Nancy L. Rose, CO Linda S. Matthingly, Investigator	10/29/10

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C. An Issue (I-0019116-FC) was created on 3/11/10 for the development of a formal corrective action for 25 different problems discovered at the DCSC between February and March 2010 related to test result entry not entered timely, second entry of confirmatory results not performed, confirmatory test results not entered and test results entered incorrectly for HCV, HTLV and anti-HBc. These problems directly affect the quality of the NDDR managed in the Philadelphia DCSC for all 36 regions. A review of Issue I-0019116-FC indicates that a proposed CAP was not approved by QA until 8/5/10. An EC is still pending; however, the success criteria documented for an EC indicates "this problem will be considered effective if there is a (b)(4) % reduction in problems for BPD Code 30-01-10, Late Test Result Entry." As of this inspection, none of these problems have yet to be closed.

Recipient Complications and Associated Problem Management Issues:

13. Job Aid 11.4.ja056, Timing Guidelines for Recipient Complication Investigations, requires that the DCSC complete a case investigation within three months of it being opened or document why the case remains open. In addition, JA 11.4.ja056 requires that a (b)(4) review of each opened case file be performed to ensure that actions are being appropriately managed. However, the nine investigations reviewed during this inspection revealed the following:

A. Case ID DCSC-P-053-TR-TRL00375, opened on 11/04/09 and closed 5/25/10, a total of 202 days, did not have a justification documented in the case notes until 2/16/10 explaining the reason the case remained opened for more than 90 days. In addition, there is no documentation that this case was being reviewed on a (b) (4) basis to "ensure that actions are being appropriately managed." This case was reviewed for completeness on 4/14/10, yet was not closed until 5/25/10.

B. Case ID DCSC-P-053-TTI-HBV00429, opened on 12/28/09 and closed 5/25/10, a total of 158 days, did not have a justification documented in the case notes until 5/25/10 explaining the reason the case was not completed within 90 days. In addition, there is no documentation that this case was being reviewed on a (b) (4) basis to "ensure that actions are being appropriately managed."

C. Case ID DCSC-P-053-TTI-HBV00651, opened on 4/28/10 and subsequently closed during the inspection on 10/6/10, a total of 157 days, did not have a justification documented in the case notes until 8/12/10 explaining the case was not completed within 90 days.

14. The DCSC has yet to implement an effective correction action associated with problems with the management of lookback investigations that were discovered as far back as 3/15/10.

A. Issue I-0019746-FC was created 4/26/10 for the implementation of a formal corrective action for 17 problems that involve the management of lookback investigations. The oldest problem was discovered 3/15/10, yet a CAP was not approved for implementation until 6/25/10. The root causes of these problems are identified as "supervisors are not consistently reviewed with their staff the open cases report generated from the (b) (4) Log" and "Operations Staff of the involved Supervisors may not have been trained to generate and use reports in the (b) (4) log database."

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The ECs are not due until 12/10/10.

B. The problem with the management of lookback investigations has continued as a trend that was later discovered on 6/30/10 (E-0831094) and the DCSC decided that a No-Formal-CAP would be created with I-0011220-NF. Yet, I-0011220 was not created until 7/29/10 and closed on 8/2/10 because it references the formal corrective action implemented in I-0019746-FC discussed above. I-0019746-FC remains open because the ECs are not due until 12/10/10.

C. Another trend (E-0864242) was later discovered on 8/31/10 for the same problem associated with the management of lookback investigations. I-0011479-NF was not created until 9/28/10 and as in 13.B. above that trend also references the formal corrective action implemented in I-0019746-FC which remains open because the ECs are not due until 12/10/10.

Health History Deferrals and Associated Problem Management Issues:

15. Failure to establish, maintain and follow written procedures that include all steps to be followed in the collection, processing, compatibility test, storage, and distribution of blood and blood components for transfusion and further manufacture purposes. Specifically, the DCSC has no adequate controls in place to ensure that the health history reports are generated daily and that failure to generate such reports will be detected promptly. (According to the DCSC management, it has been operating with draft work flows for the health history report review process.) For example,

After a request was made for health history deferral records for 7/10 for three regions, the DCSC informed FDA that it discovered that the DCSC failed to generate five requested reports; therefore, it failed to conduct a review of each listed donor with prior donations for potentially unsuitable blood components requiring quarantine, retrieval, and consignees notification in accordance with System 11 procedures. (The DCSC opened E-0869169 to address the problem discovered as a result of the FDA request for these records.) The DCSC review of the missing reports found that there were deferred donors that had not been managed appropriately. For example, health history deferral reports for the following collection dates and regions were not generated and reviewed to identify the potential need for product retrieval and consignee notification:

A. Region 035, collection date 7/7/10 was completed 9/9/10. The report included two donors with prior donations requiring management under system 11.

B. Region 029, collection date 7/31/10.

C. Region 029, collection date 7/8/10. This report had three donors with prior donations requiring management under System 11.

In addition, the investigation of E-0869169 found that there were additional missing health history reports (approximately three at the Philadelphia facility and approximately 12 at the Charlotte facility.)

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16. The Philadelphia DCSC facility discovered approximately 18 level 3 problems coded as QC-90-01-05—failure to manage potentially non-conforming products (product not released). A review of those problem records found problem management deficiencies. For example,

A. The DCSC failed to conduct an adequate root cause analysis, to develop an appropriate CAP, and to conduct an EC for a level 3 problem. E-0790730 was discovered on 4/16/10 and remained open as of 10/7/10. The problem description states that a hold was not applied to an in-date product for a donor with an XW3 assertion. The root cause is described as "Due to the peculiarity of this case, [a supervisor] was puzzled which resulted in unclear guidance to a new staff." The CAP is describes as the supervisor "recognizes how to appropriately handle these types of cases so that he can better communicate to the staff the appropriate actions that are required." QA approved the CAP on 5/21/10. I-0020041-FC states it was implemented on 5/21/10. The EC was due on 8/27/10, but as of 10/7/10 had not been completed.

B. The DCSC failed to implement a CAP in a timely manner. E-0751845 was discovered 2/16/10 and remained open on 10/7/10. The problems description states no immediate gain control was performed for a DRIR-related infection. The documented root causes are short-staffed and staff are feeling overwhelmed and frustrated. In I-0019143-FC, the CAP was to develop a DRIR process to have more structure and to develop a phone schedule. QA approved the CAP on 3/17/10, but it was not implemented until 9/27/10.

C. The DCSC failed to complete EC in a timely manner. E-0746476 was discovered 2/5/10 and remained open on 10/8/10. The problem description was no hold applied and the region was not notified to gain physical control of an imported component. The documented root cause was the staff failed to identify the importance of gaining physical and electronic control of the component, "due to her lack of knowledge with the American Red Cross and DCSC." I-0018941-FC documents the CAP as "staff will be counseled and will continue to gain experience;" training will develop a communication; and training will conduct a refresher. QA approved the CAP on 3/10/10. Implementation dates are documented as 3/10/10, 5/3/10, 7/26/10, and 7/27/10. EC due dates were 9/7/10 and 9/9/10, but were not completed until 10/8/10.

Problem Management – Missed Timeframes:

17. The DCSC does not always meet the established timeframes required in the System 10 Problem Management Procedures and in the Decree. A query for the period 1/1/10 through 9/22/10 of the problem management files maintained in ARC's automated problem management system, known as SmartCAPA, was requested on 9/22/10 and revealed the following:

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

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SmartCAPA Query Activity	**Requirement**	**Number of Problems Found in SmartCAPA**
48-hour notification to consignee not performed, not complete and/or not timely for the distribution of unsuitable blood or blood products	System 10 and Paragraph X.E of the Decree	90
48-hour notification to FDA's Baltimore District Office not performed, not complete and/or not timely	System 10 and Paragraph X.E of the Decree	22
45-day notification (Biological Product Deviation Reports) to CBER	System 10 and 21 CFR 606.171	7
45-day notification to FDA's Baltimore District Office not performed, not complete and/or not timely	System 10 and Paragraph X.D of the Decree	3
Problems logged into SmartCAPA greater than five days after discovery	System 10	193
QA review of problem not performed within five business days of receipt in QA	System 10	8
Development of CAP/approval of CAP not timely	System 10	1

10/29/10

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	Linda S. Mattingly	Nancy L. Rose, CO Linda S. Mattingly, Investigator	10/29/10