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December 15, 2010

Evelyn Bonnin
District Director
Baltimore District Office
United States Food and Drug Administration
6000 Metro Drive, Suite 101
Baltimore, MD 21215

Dear Ms. Bonnin:

Attached to this letter is the American Red Cross response to the observations identified by Investigators Linda S. Mattingly and Nancy L. Rose and listed on the Form FDA 483 presented at the conclusion of the September 2 – October 29, 2010 Food and Drug Administration inspection of the American Red Cross facility at 700 Spring Garden Street, Philadelphia, PA 19123 (CFN/FEI To Be Determined).

The Donor and Client Support Center is committed to achieving the highest standards of quality in all of the products and services that we offer. The American Red Cross is working to address the issues identified by the investigators for which additional actions are warranted.

If you need any further information, please contact Celia Clifford, Vice President, Field Quality Assurance, at 770-852-4226.

Sincerely,

J. Chris Hrouda
Executive Vice President
Biomedical Services

Attachment 1, DCSC FDA Form 483 General Response
Attachment 2, DCSC FDA Form 483 Observational Responses
Exhibits I through XV on CD

cc: Linda S. Mattingly, Investigator
Nancy L. Rose, Compliance Officer
Julie Hall, Interim Senior Director, Quality, Donor and Client Support Center
Kay Crull, Vice President, Manufacturing and Donor Management
William Moore, Senior Vice President, Biomedical Headquarters
Kathryn J. Waldman, Senior Vice President, Quality & Regulatory Affairs
Celia Clifford, Vice President, Field Quality Assurance

Exhibit List

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Donor and Client Support Center (DCSC)
FDA Form 483
General Response

The FDA Form 483 raises a number of broad issues regarding Red Cross' compliance with regulations, the amended Consent Decree, and Red Cross SOPs. Specifically, the Form 483 raises concerns about four areas:

I. Biomedical Services Headquarters' (BHQ) oversight and control
II. DCSC Operations' managerial and Quality Assurance (QA) oversight
III. Consolidation of donor management functions into the DCSC
IV. Implementation of Problem Management

Red Cross is committed to providing the resources necessary to address these issues and to ensure that the DCSC operates effectively and in compliance with all regulations, policies, and procedures. Red Cross has analyzed these four areas, identified what factors contributed to the issues that occurred within each area, and initiated actions to address them. Red Cross' goal is to ensure that going forward BHQ: provides an appropriate level of oversight for all major initiatives so that they are implemented successfully; ensures that facility management teams are effective; and monitors pertinent metrics to identify performance issues at the earliest possible opportunity.

In order to ensure that all concerns with the DCSC have been identified and appropriate actions taken to prevent recurrence, BHQ will hire an external consulting firm to perform an evaluation of the issues that occurred with the DCSC. The consulting firm will determine whether Red Cross has identified all factors contributing to these issues, verify that Red Cross has taken appropriate actions, and evaluate whether similar risks to future initiatives have been mitigated. BHQ will select the external consulting firm to lead this effort during the first quarter of calendar year 2011.

The analysis of the four areas listed above and the actions that have been or will be taken are described below. These actions are in addition to those that are described in response to the individual FDA Form 483 observations in Attachment 2.

I. BHQ Oversight and Control

BHQ did not effectively manage consolidation of the donor management functions into the DCSC. BHQ managed the donor management consolidation using existing mechanisms, including the system Quality and Compliance Oversight Committee (QCOC) and the Field Operations Group (FOG), to provide oversight. However, in retrospect, these mechanisms proved to be inadequate. In the future, Red Cross will manage key initiatives using program management principles, with appropriate governance structures and oversight established at the outset, similar to those established for management of the BioArch program. This will include the establishment of a set of metrics for monitoring performance and formal readiness reviews for key stage gates using these pre-defined metrics.

BHQ relied on the reports provided by the DCSC management in making its assessments and in providing updates to the Quality and Regulatory Compliance (QRC) Subcommittee and Audit & Risk Management (ARM) Committee of the Board of Governors. The QRC did raise concerns regarding DCSC staffing levels and whether transition of additional regions should continue to occur. BHQ leadership evaluated the data provided by DCSC management which showed that actions had been taken to address recognized challenges, improvement in current compared to historical performance, and adequate staffing levels. The consolidation timeline was extended to allow new staff to become more proficient, and DCSC management expressed confidence that the DCSC could successfully complete the consolidation by March 2010. Based on the data presented and the concern regarding the ability to retain regional donor management staff whose jobs were being eliminated, BHQ senior leadership authorized the transition of the remaining regions to continue. In retrospect, this was not the right decision.

BHQ now recognizes that the DCSC management reports were insufficient in determining a complete and accurate picture of DCSC performance. Prior to starting the consolidation, BHQ did not establish a set of metrics for monitoring the process. There were limited metrics for donor management performance in the regions that could have been used to establish a baseline for comparison. BHQ is defining the metrics that will be used to monitor current DCSC operations and adherence to Problem Management (PM) SOPs and timelines. These metrics will be added to the DCSC Dashboard and, depending on each metric, will be updated (b) (4) or (b) (4) The updated Dashboard will be in place no later than December 20, 2010. To help ensure that all concerns are identified and addressed at the earliest possible time, BHQ has dedicated a staff member from the internal quality audit team to independently monitor DCSC operations, identify issues requiring attention, and provide feedback to operations, QA management, and senior leadership. A schedule of planned activities has been developed through February 2011 and will be updated as needed. As of November 29, 2010, this staff member is onsite full-time in Charlotte, but will make periodic visits to Philadelphia. In addition to this ongoing monitoring, the DCSC performance will be evaluated through routine and special quality audits as needed.

As the final regions' donor management functions were transitioned to the DCSC, performance problems increased and the DCSC struggled to manage the workload. BHQ requested a special audit, which was held in Charlotte from (b) (4) The audit was conducted to evaluate corrective actions in response to FDA inspections and internal audits and evaluate processes and current performance. On July 7, 2010, based, in part, on the results of this audit and the PM audit in April, BHQ directed development of a Compliance Improvement Strategy (CIS) for the DCSC. The CIS, provided in Exhibit I, was approved on September 30, 2010 and addresses compliance issues in eight functional areas:

1. Staffing/Training/Proficiency
2. Component Retrievals

3. Donor Adverse Reactions
4. Recipient Reactions
5. Donor Management
6. Problem Management/Quality Assurance
7. Records Management
8. Document Management

CIS teams investigated the problems in each of the above areas, performed root cause analysis, and developed corrective action plans. The teams created sub-plans for each area that described their investigations and CAPs, and submitted them to the QCOC for review and approval on November 12, 2010. The QCOC provided comments to DCSC Management on November 29, 2010, and the DCSC will discuss its responses to these comments at the QCOC meeting on December 17, 2010. Red Cross will provide the individual sub-plans, once final, upon request.

On September 7, 2010, the President and Executive Vice President of Biomedical Services and the Senior Vice President of Quality and Regulatory Affairs met with DCSC management in Charlotte to review the CIS plan. This same senior leadership team, along with the Vice President and Deputy General Counsel, began weekly meetings with DCSC leadership on October 25, 2010. The objective of these meetings is to monitor the DCSC's progress on key initiatives, such as increasing staffing levels, clearing the backlog of cases pending process verification, and assisting with resolution of operational and compliance issues as they are identified.

In addition, BHQ senior leadership visited both DCSC locations recently, Charlotte on November 22, 2010 and Philadelphia on December 2, 2010. During these trips, senior leadership met with all available staff in a series of meetings to assure them of BHQ's commitment to the DCSC and to get their input on what they need to be successful. The discussions were open and identified additional areas requiring attention, including the approach to training, communication with staff, and the proficiency level of staff and supervision. Staff were encouraged to assess their own level of comfort in performing their duties, to identify any additional training they needed, and to discuss their self-assessment with their supervisors. Per procedure, staff will be removed from performing any tasks for which they or their supervisors determine additional training is needed to achieve competency.

Based on the issues identified by FDA and Red Cross audits, as well as ongoing discussions with DCSC management and staff, BHQ has decided that the DCSC will be placed under a Modified Compliance Improvement Strategy (MCIS) rather than a CIS in order to address the seriousness of these issues. The areas of focus and additional actions planned as part of the MCIS, in addition to those already identified in the CIS, will be determined by January 14, 2011. At a minimum, the increased areas of focus will include formal staff assessments and training. An assessment of all management, operational, QA, and PM staff will be performed. Although it is not possible to reduce workload volume as was done in the Greater Chesapeake & Potomac and Southern Regions, staff will be taken off line for additional training as deemed necessary. While planning for the

MCIS is in progress, the DCSC will continue with all corrective actions included in the approved CIS.

As noted above, BHQ relied on existing mechanisms to monitor DCSC performance during the consolidation, including the functional management reviews, the QCOC, QA Audit reports, and reviews of FDA Form 483 observations. BHQ has determined the need, and is now evaluating, DCSC performance by analyzing collectively an enhanced set of metrics. This provides a more robust process of review and will help to ensure that overall DCSC performance is well understood.

Based on previous analysis performed, BHQ recognized that the system for monitoring Biomedical Services system-wide performance needed strengthening and must include a formal mechanism to evaluate performance through analysis of available metrics collectively rather than individually. At the direction of the President and Executive Vice President of Biomedical Services and the Senior Vice President of Quality and Regulatory Affairs, a task force is being established to create an integrated process by which quality metrics will be analyzed collectively and escalation triggers defined for increased oversight by either the division or system-level QCOC based on this evaluation. A Division Vice President and a Senior Director of Quality are leading this task force.

The President, Biomedical Services, will create a department that will have ongoing responsibility to analyze quality metrics collectively to determine the state of compliance for individual facilities, processes, and Biomedical Services, overall. This department will be led by a Vice President of Compliance, hired from outside Red Cross, who will serve as the Chief Compliance Officer for Biomedical Services and report directly to the President, Biomedical Services.

II. DCSC Operations' Managerial and QA Oversight

The DCSC managerial and QA oversight was not sufficient to ensure that the DCSC was operating in a state of control and in compliance. Therefore, BHQ determined that the oversight needed strengthening and made the following organizational changes in the DCSC, effective November 3, 2010.

- The Vice President of Manufacturing has assumed leadership of the DCSC and is now the Vice President of Manufacturing and Donor Management. This individual has a track record of proven leadership and outstanding quality and compliance performance.
- The Executive Director, Donor Management, is now the Senior Director of Donor Management Operations Support and reports directly to the Vice President of Manufacturing and Donor Management.
- The Senior Director of Quality for the DCSC is no longer employed at the Red Cross. The Director of Quality for the Mid-Atlantic Region is serving as the interim Senior Director of Quality for the DCSC with oversight of QA and PM. She is located in Charlotte.

- The Problem Management Director is no longer overseeing the Problem Management Department and is working on several projects, including oversight of problems managed remotely. The PM Manager from the Northeast Pennsylvania Region is providing oversight for the day-to-day work and has been onsite in Charlotte since December 1, 2010.

In addition, to provide additional quality support in the interim, the following actions have been taken:

- The Director of Quality, Central Ohio Region, has responsibility for monitoring the progress of actions defined in the CIS (soon to be MCIS) and the effectiveness of those actions.
- The Senior Director of Quality, Mid-America Division, has been on-site at the DCSC to review DCSC QA and PM tasks, determine how regional QA and PM staff can provide temporary support for these tasks, and allocate those regional resources accordingly.
- The Director of Quality, Penn-Jersey Region, is providing quality support and oversight for the Philadelphia DCSC location, working closely with the Director of Quality for the Mid-Atlantic Region.

The immediate focus of the new QA management team is to help ensure that appropriate actions are taken in response to the FDA 483 observations, such as issues concerning the backlog of cases that require process verification, the backlog of donor complication files that require medical and/or final quality review, and overdue Quality System Reviews. The team will also perform regular operations walkthroughs, providing increased QA oversight for Operations. As mentioned above, a member of the internal quality audit team is onsite in Charlotte monitoring operations, identifying issues, and providing feedback.

III. Effective Consolidation of Donor Management Functions

The consolidation of donor management functions into the DCSC was not effectively executed. Red Cross has identified several contributing factors, including: number of staff resources; staff proficiency; supervisors' level of experience; and tools for tracking work status. These factors are discussed below.

Number of Staff Resources

Red Cross underestimated the workload and the number of staff resources required to perform the work. The staff turnover rate has averaged (b)(4)%, which is higher than the historical turnover rate for the donor management function in regional facilities. The ratio of tenured to new staff is lower than anticipated and the impact of so many new staff is significant. Many supervisors are relatively new to their role and have limited experience in donor management. The DCSC management team recognized these staffing issues and temporarily stopped the consolidation from March - April 2009. Two regions transitioned in May 2009, but because the challenges persisted, the DCSC paused again in June - July 2009. This allowed the DCSC to assess their performance to date, determine what

changes were necessary, and allowed staff to gain additional experience, improving their proficiency and efficiency, before taking on more regions' work. DCSC management delivered workshops on areas where staff were having difficulties, provided customer service training, presented performance data to staff to promote improvement, and worked with supervisors on meeting expectations. Performance improved and the problem rate declined throughout 2009.

The performance improvement seen in 2009 was not sustained after the remaining regions transferred in early 2010. Staffing challenges continued. DCSC management determined that it needed to hire (b) (4) staff who would be dedicated to answering donor eligibility calls. In May 2010 a time study was completed that verified that the number of call staff identified by management was adequate. The (b) (4) new staff were hired and on board by June 2010. This action allowed the remaining staff in the Donor and Client Support Specialist (DCSS) Teams to focus on case investigations without interruption from eligibility calls.

Other areas were also understaffed and the DCSC has hired a significant number of new staff since September 2010. A hiring plan was developed to ensure that there will be a sufficient number of staff, taking into consideration the turnover rate and that many staff are new and will not be fully proficient for several months. DCSC management has also decided to create a team of (b) (4) staff members dedicated to performing process verification and some of the newly hired staff will join this team.

As noted in the FDA Form 483, a backlog of cases pending process verification exists. In order to clear the backlog, DCSC management has enlisted the help of experienced staff from several regions who are dedicated to performing process verification. The sites and the number of FTEs are listed in the table below.

Supplemental Site	Staff Mix*	Start Date
St. Paul	(b) (4)	7/13/2010
Dedham		9/14/2010
Florida		10/11/2010
Boise		10/25/2010
Johnstown		11/15/2010
Louisville		11/15/2010

*FT = full-time; PT = part-time; FTE = full-time equivalent

In addition, a contract was signed with (b) (4) consulting firm, for staff augmentation. (b) (4) staff from (b) (4) started November 15, 2010 and (b) (4) more started November 29, 2010. These staff are located in the Charlotte facility and are performing process verifications with onsite operational, quality, and problem management support.

Staff Proficiency

The DCSC was initially implemented under a region-focused model. Staff were divided into teams and each team performed all functions for the regions assigned to their team.

This meant that staff had to become proficient in all areas quickly in order to be successful in their jobs. This model contributed to the issues seen and may have also been a factor in employee satisfaction and staff turnover. Therefore, The DCSC changed its structure from one that was region-focused to a functional team model. The functional model allows staff and supervisors to focus on and develop process expertise in a specific functional area. The planning began late in 2009 and the Philadelphia DCSC transitioned to the new model on June 21, 2010, followed by the Charlotte site on September 27, 2010.

Supervisors' Level of Experience

Many of the supervisors are new to the supervisory role and to donor management activities. In the fall 2010, a Supervisory Academy was developed to augment the skills of the supervisors in managing staff. Two BHQ Organizational Development and training professionals have designed and are delivering the courses in the Academy. They are designed to assess each supervisor in a group setting to identify their strengths and weaknesses and then develop an individual plan to support development. Starting in September 2010, two full day training sessions have been delivered focused on coaching and giving feedback, building collaborative relationships, and maintaining appropriate supervisory documentation. Each month supervisors are provided with information that focuses on a specific skill, such as how to supervise former peers.

Tools for Tracking Work Status

DCSC supervisors did not have all the tools needed to track incoming work and to ensure its completion. The tools that were effective in a regional facility with lower case volume and more experienced staff proved to be less effective in a consolidated center with a large case volume. Several tools have been or will be implemented to assist supervisory staff in overseeing the work, reconciling that all work expected is received, and verifying that all activities are completed. Specific tools are described in the responses to the pertinent observations in Attachment 2.

IV. Effective Implementation of Problem Management

The DCSC did not effectively implement the Problem Management system. Initially, the DCSC PM department was led by a manager responsible for both locations, Charlotte and Philadelphia. As the workload was better understood, BHQ QA leadership determined that the PM managerial oversight needed strengthening. In February 2009, a Problem Management Director (PMD) was transferred from a Red Cross division to lead the DCSC PM department.

In addition, the PM staffing levels were insufficient to handle the volume of post donation information (PDI) problems and level 2/3 problems. DCSC PM staff log and manage approximately 1,100 PDI problems per month. Ten to twelve percent of DCSC problems require a level 2/3 investigation compared to approximately five percent of regional problems. There were not enough PM staff trained to manage level 2/3 problems. (b)(4) staff members were added in 2009 to manage the increasing PM workload

as additional regions were transitioned to the DCSC. In late 2009, a separate group within PM was established to specifically manage PDI problems. In May 2010, a PM Manager with QA experience was hired to provide oversight and mentor the PM staff managing level 2/3 problems. Today, the PM department has a total of (b) staff consisting of the PMD, a PM analyst, a PDI group, and PM staff. There are (b) (4) staff in the PDI group, including the manager. There are (b) (4) PM staff, including (b) PM managers, performing core PM duties.

As additional regions transitioned to the DCSC in 2010, the workload for PM and the number and age of open problems increased. Although the PM staffing level has been increased significantly, many of these staff are relatively new and will become more proficient over time. The processes in place in the DCSC and the interactions among Operations, QA, and PM staff are currently inefficient and also contributed to the difficulties in managing the workload. Operations staff were not fully engaged in the PM process as they were also struggling with their workload. In July 2010, Red Cross implemented the first of four PM SOP changes, referred to as the Culture of Collaboration. This package included the standard manual problem form and a requirement for Operations to complete the form and review it prior to submission to PM. This change was not well implemented at the DCSC.

In June 2010, BHQ assigned Principal Investigators (PIs) to provide oversight of DCSC problems and to mentor staff in the problem solving process.

As of August 2010, management of DCSC level 1 problems has been assigned to the South Central Division PM staff. Division staff will triage and assign all new incoming work, manage all level 1 problems and approximately [redacted]% of PDI problems. As of October 15, 2010, approximately [redacted]% of problems that require a level 2/3 investigation have been assigned to PM staff in other divisions. This will allow BHQ to assess the PM staff, create individual development plans as needed, and provide additional training and mentoring. The support from the South Central Division will continue until the DCSC PM staff are fully proficient and can manage their workload independently.

On December 1, 2010, an experienced regional PM Manager was assigned to the DCSC to assist in oversight of the day-to-day work. This person will provide input for methods to improve efficiency and effectiveness associated with the management of problems and will develop a robust monitoring process. The draft monitoring process will be defined by December 10, 2010, and the final process is targeted for completion by February 2011. In addition, there is a PM Manager in each location who is supervising the problem management staff.

By January 2011, (b) (4) PM staff, (b) (4) [redacted], will begin working with the DCSC Operations supervisors to improve the quality of the information documented on the Manual Problem Forms and reduce the number of forms that must be returned to Operations for additional information. In early 2011, staff from BHQ PM will present the "Power of Three" workshop to all DCSC Operations, PM, and QA staff. This workshop emphasizes teamwork and collaboration between the groups. These actions

will strengthen relationships between Operations, Problem Management, and Quality by promoting involvement in areas of quality and compliance, root cause analysis, and Corrective Action Plan (CAP) development and implementation.

Operations staff are now required to attend all scheduled PM meetings for root cause identification and corrective action development. This will ensure that Operations staff participate actively in the development of the corrective actions and the timelines for implementation and assume ownership for problem resolution.

The DCSC included a plan within the CIS to further improve the PM process. The CIS team for PM and QA improvement completed a detailed failure mode analysis and developed corrective actions to address the identified failure modes. The response to observation 3 provides details regarding the planned CIS actions.

Summary

In addition to the actions described above, the DCSC has developed actions to address the concerns cited in the individual observations on the FDA Form 483. These actions are described in Attachment 2 of this response.

American Red Cross
Donor and Client Support Center
700 Spring Garden Street
Philadelphia, PA 19123
Response to Observations
Food and Drug Administration Inspection
DCSC Philadelphia, PA
September 2 – October 29, 2010
Investigators: Linda Mattingly, Nancy Rose

Management Control:

Observation 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 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, and 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 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 yet 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 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 staff 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 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."***

D. ***In July 2010, senior management placed the DCSC on 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).

Response to Observation 1: (APMS # E-0900152)

Please see sections I and II of Attachment 1, *FDA Form 483 General Response*, of this response.

Observation 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 "...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 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 transition; 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.

Response to Observation 2: (APMS # E-0900174)

Please see section II of Attachment 1, *FDA Form 483 General Response*, of this response.

Response to Observation 2.A
Donor Status Change Records (DSCR), Component Status Change Records (CSCR) and/or Component Investigation Forms (CIF) require documented process verification in accordance with Work Instruction (WI) 11.3.028, *Process Verification*. Process verification, performed after all required actions are completed, confirms or substantiates that the process was followed, all tasks were performed, appropriate actions taken, required documentation is provided or available, and the process is complete.

A reported donor complication is documented on the Donor Reaction and Injury Record (DRIR). The investigation and communication with the donor requires a medical assessment either by the regional Medical Director in accordance with WI 15.3.055, *Performing Final Case and Donor Suitability Assessment*, or by Donor and Client Support Center (DCSC) case investigators in accordance with WI 14.3.174, *Performing Final Case and Donor Suitability Assessment.* This review determines if donor deferral and/or product retrieval is required. Subsequent to documentation of the medical assessment, a trained DCSC Operations staff person performs the final review (Final Quality Review) of the documentation and actions taken in accordance with WI 14.3.178, *Final Donor Complication Review*, before the donor complication case is closed.

There is a backlog of case files outside the normal caseload that remain open pending these final reviews (process verification, medical assessment and/or final quality review). Management will establish a case closure priority based on risk and file age. As stated in the *FDA Form 483 General Response,* additional Red Cross and contract staff have been hired to clear the backlog of cases. These staff are being assigned to review and close cases according to the established priority.

Response to Observation 2.B
Subsequent to this inspection, DCSC staff identified that Quality Process Reviews had been performed in the Philadelphia location. Quality Process Reviews for 2008, 2009, and 2010 through July, were completed as indicated in the following table.

System	Month/Year completed	Charlotte	Philadelphia
System 1 Management	(b) (4)		
System 10 Managing Customer Concerns			
System 14 Donation Recruitment and Qualification Management			
System 11 Suspect Product Review – Post Donation Information			
System 4 Training and Personal Competency			
System 7 Information and Data Management			
System 6 Validation			
System 20 Quarantine/Lot Release/Labeling			
System 3 Policy and Procedure Management			
System 11 Suspect Product Review			
System 22 Information Technology			
System 1 Management			
System 3 Policy and Procedure Management			
System 7 Information and Data Management			

Red Cross apologizes for not having these records available during the inspection and will provide copies of these Quality Process Reviews to the FDA upon request.

The following system reviews were included in the 2009 Quality Process Review schedule but were not completed:

- System 1 *Management*
- System 2 *Quality Assurance*
- System 5 *Facilities*
- System 15 *Collections*
- System 19 *Finished Product QC*

Three systems reviews were performed in 2010 prior to the start of this inspection. The remaining systems reviews will be completed by the end of 2010 and the summary reports will be distributed in January 2011:

- System 2 *Quality Assurance*
- System 4 *Training/Personnel Competency*
- System 5 *Facilities*
- System 9 *Change Control*
- System 10 *Problem Management*
- System 11 *Suspect Product Review*
- System 12 *Supplier Quality*
- System 13 *Material Management*
- System 14 *Donation Recruitment and Qualification Management*
- System 15 *Collection*
- System 22 *Information Technology*

A problem, E-0890533, was opened on October 15, 2010 for failure to perform these Quality Process Reviews.

Response to Observation 2.C
As stated in Directive 02.2.011, *Process for Developing a Facility Quality Plan*, the Facility Quality Plan (FQP) and associated documents serve as the primary document for facility operations and the Quality Assurance department for use in project planning, transition to a new/renovated or acquired facility, and decommissioning of an existing facility. The Philadelphia and Charlotte DCSC facilities have approved FQPs [see Exhibits II and III]. The first date of operation for the Charlotte facility was March 28, 2008 and the FQP was put in place on March 27, 2008. The first date of operation for the Philadelphia facility was May 19, 2008 and the FQP was put in place on May 15, 2008. As of November 8, 2010, Quality Assurance staff in Charlotte and Philadelphia have been made familiar with the FQP and where the plan is located within each facility. Red Cross apologizes for not providing these plans to the investigators during the inspection.

Observation 2.D
Red Cross recognizes that the seriousness of the DCSC issues were not clearly documented in the Red Cross Quarterly Quality Assurance (QA) reports until the January-March 2010 report. The QA Report is not used as the primary mechanism to inform senior leadership about significant performance issues because the report is issued quarterly based on data from the previous quarter. Other mechanisms are used to ensure that senior leadership is kept current and the DCSC Management provided updates to Biomedical Services senior leadership at the Field Operations Group meetings, Management Reviews, and the Quality and Compliance Oversight Committee. However, as noted in the general response, the DCSC management reports were insufficient in providing senior leadership with a complete and accurate picture of DCSC performance. Regardless, the QA Report should have included information regarding the DCSC issues and actions that had been taken or were planned to address them. In the future, BHQ QA leadership will ensure that these reports are comprehensive.

Observation 2.E
The QA and PM assessments included staff interviews, a review of problems managed by the PM staff or reviewed by the QA staff, and four data analysis exercises for the analysts. Within two weeks of completing the QA and PM staff interviews in a DCSC site, a list of issues was compiled and provided to senior quality leadership. [See Exhibits IV through VII] An individual summary of the assessment performed for each DCSC QA and PM staff person was provided to both the Senior Director Quality and the Problem Management Director at the DCSC in February 2010. They worked with each staff person to develop an action plan, as appropriate, to address any identified issues. The final summary reports for the DCSC QA and PM assessments were provided in April 2010. PM and QA staff are currently being mentored by BHQ Problem Investigations staff.

Observation 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 in 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

<u>NOTE:</u> 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 problems management. The corrective action plan (CAP) described including 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.

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-00551794, I-0013588-FC (discovered 3/27/08, closed 5/4/10) and determined that root causes included inadequate staffing, only (b) (4) ***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-0680167, 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 10/29/10. 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 documents 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-00017441-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.***

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-00202482-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 6/5/090, 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 states 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 CPA included time studies by a lean engineer, developing a backlog plan, clarifying DRIR time frames, and hiring (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.***

Response to Observation 3: (APMS # E-0900189)

Please see section IV of Attachment 1, *FDA Form 483 General Response*, of this response.

Red Cross is committed to improving the Problem Management (PM) process to ensure that problems are corrected and do not recur. Meeting timelines, performing thorough investigations, and developing effective corrective action plans to reduce/eliminate problems are critical to a successful Problem Management System. The recently approved Compliance Improvement Strategy (CIS) plan includes a focus on Problem Management activities. The CIS team for PM and Quality Assurance (QA) improvement has been actively working to identify corrective actions.

In October 2010, in order to better understand the issues within Problem Management, the CIS team completed a detailed failure mode analysis for FDA 483 observations, internal audit findings, and problems logged related to Problem Management requirements. The following failure modes were identified:

Failure Mode	% of the Baseline
Timelines not met**	(b) (4)
Inappropriate root cause/lack of appropriate documentation of root cause/no evidence of root cause tools	
Team not convened/participants not documented/meeting minutes not documented	
Corrective Action (CA) does not clearly map to Root Cause (RC)	
No baseline established/no documentation of data review	
Inappropriately ranked Effectiveness Check (EC)	
Inappropriate use of No Formal CAP (NFC) Issue type	
Total	**100%**
**Timelines not met includes: 1. Late logging of problems; 2. Corrective Action Plan (CAP) not submitted within 30 day requirement; 3. QA review not performed within 5 business days; 4. CA not performed within the required timeline; 5. EC not performed within the required timeline	

Actions initiated because of the CIS investigation will focus on improving skills of current PM and QA staff, ensuring timely management of problems, and ensuring that corrective actions are robust and effectively implemented to prevent recurrence. To accomplish this, additional training and mentoring of the DCSC PM and QA staff will occur.

1. (b) (4) additional PM staff will be trained to manage Level 2/3 problems
2. Current PM and QA Staff will receive training on the newly revised training materials 10.4.tc068_tip, *Investigating Level 2/3 Problems and Developing Corrective Action Plans-tip*. [See Exhibit VIII] This is a "back-to-basics" program designed to refresh problem managers on the steps for appropriate investigation of problems including detailed root cause analysis. This program will also provide instruction on developing effective Corrective Action Plans (CAP) including Effectiveness Checks (EC). This training occurred at the Philadelphia location during the week of November 29, 2010 and at the Charlotte location during the week of December 6, 2010.
3. Current PM and QA staff mentoring began during the week of December 6, 2010 after staff completed training on 10.4.tc068_tip described in item 2 above. PM and QA staff are paired to facilitate mentoring and to develop strong working relationships between the problem managers and the QA reviewers. The mentoring pairs will work on current problems with experienced mentors from BHQ Problem Management. Mentoring will focus on:
    - Using problem solving tools on current problems
    - Facilitating team meetings including note taking
    - Developing and performing effectiveness checks, including evaluation of baseline data
    - Managing specialized problems, including Significant Corrective Action problems
    - Developing effective cross-facility problem management skills

The goal of this plan is to ensure PM staff, in partnership with QA reviewers, are adequately trained and equipped to perform assigned functions. Training, mentoring, and monitoring

staff progress through the investigation and review processes as outlined in System 10, *Problem Management* will accomplish this goal. In turn, this plan will result in problem files that meet System 10 documentation requirements and contain evidence that: 1.) problem investigations are conducted appropriately for Level 2/3 problems; 2.) failure modes map to probable or root cause, corrective actions; and 3.) effectiveness measures ensure each problem is appropriately addressed.

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

The observations included in this section of the FDA Form 483 are related to managing problems associated either with documentation errors on the Donor Reaction and Injury Records (DRIR), missing DRIRs, or missing or untimely Medical Director or final quality reviews and will be discussed in the response to Observations 4 through 6, respectively. In addition, the response to Observation 6 will include all actions taken to date or actions proposed for the future related to management of DRIRs.

Observation 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.***

   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[1] under BHQ system trend E-0603257. QA approved the proposed CAP (no additional corrective actions) on 2/18/10 and the exception was closed on 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***

[1] The dates that corrective actions for BHQ system trend were implemented are November 12, 2009 and January 31, 2010.

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 [redacted]% 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 requirement 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.***

Response to Observation 4: (APMS # E-0900194)

This observation contains two concerns: 1) Inadequate or untimely management of problem investigations related to documentation errors or omissions on the DRIR and 2) Errors or omissions on the DRIR continue to occur.

An evaluation of all problems referenced in this observation was completed and the main issues with managing the problems have been identified as:

- Failure to triage incoming work and to assign ownership of problems in a timely manner
- CAP was not developed within thirty days/ Ineffective proactive monitoring of Level 2/3 problems requiring a CAP
- Incomplete investigation of the problem
- Problems not linked appropriately in the Automated Problem Management System (APMS)
- Inadequate QA review/ QA approved extension requests without sound rationale

These failure modes are included in those identified during the Root Cause Analysis performed for the CIS for PM and QA. Please refer to the corrective actions outlined in the response to Observation 3 above. The actions being taken under the CIS should help the PM staff avoid these types of errors when managing problems and trends in the future. In addition, the assistance being provided by other Divisions will help ensure timely triage and management of problems until the DCSC PM department is operating efficiently and can be self-sufficient in managing the incoming workload.

Response to Observation 4.A: Red Cross has recognized that the DCSC inappropriately linked the facility trend E-0664347 to the systemic trend E-0603257. The DCSC inappropriately closed the local trend E-0664347 prior to confirming that any actions taken in the systemic trend would address the failure modes identified in the DCSC local process. Under the System 10 procedures, it is not appropriate to link a local trend to BHQ systemic trend since a facility is expected to take actions locally to mitigate and correct problems whenever possible. The DCSC currently has an open trend problem E-0811555/I-0020944-FC to further investigate issues related to completion of the DRIR.

Response to Observation 4.B:
Red Cross has reviewed E-0603257, BHQ Systemic Trend for Donor Reaction Injury Record (DRIR) documentation errors, and believes that the systemic trend was managed in accordance with all System 10, *Problem Management*, requirements and timelines. The trend investigation and analysis focused on documentation errors on the DRIR form that is five pages in length with twelve distinctive sections. Detailed stratification of the problem data was performed to isolate specific fields and sections of the form that caused the majority of errors. A corrective action in a previous systemic trend (E-0204526 logged in October 2007) provided a revision to certain sections of the form with (b)(4)% reduction in errors seen for failure modes addressed by the revision. The corrective action for trend E-0603257 (logged in June 2009) did not include addition changes to the DRIR form since there is a donor complication process and form redesign included in BioArch Release 1 implementation. Therefore, during CAP development, the investigation team determined that, in the interim, all staff trained to document or review donor complications would receive clarification of the form instruction requirements for the most problematic fields of the DRIR. Since the corrective action for this problem was not preventative and the failure mode addressed by the corrective action was related to a manual process, the success criterion for this problem was set at (b)(4)% reduction. The clarification was released in Communication (b)(4) Update #828 on November 24, 2009. The investigation team elected to use this action for the incremental improvement that could be obtained since a more substantive change was already incorporated into BioArch Release 1 and Red Cross anticipated implementation of Release 1 beginning in the fall of 2010.

The EC was appropriately designed per WI 10.3.15, *Developing and Performing Effectiveness Checks*, and demonstrated a (b)(4)% overall improvement for all facilities of failure modes addressed by the corrective action.

Response to Observation 4.C:
The investigation in I-0020944-FC is still open pending completion of the interim and sustained effectiveness checks.

See the response to Observation 6 below for actions taken or proposed to address general DRIR management.

Observation 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.

Response to Observation 5: (APMS # E-0900205)

This observation describes the investigator's concern regarding delays in performing root cause analysis and developing corrective actions for missing DRIRs.

The problem E-0836426 cited in this observation is related to missing DRIRs for donors with an X category complication code and is being managed by a BHQ Problem Investigator (PI). The problem investigation in E-0836426 focused on activities performed at the DCSC, as well as handoffs of information between the DCSC and other facilities, including BHQ. The scope does not include care of donors at the collection site. The BHQ PI has been actively working on this problem in conjunction with DCSC and Red Cross Medical Office Hemovigilance Program staff since July 31, 2010. The PI requested extensions for CAP development due to the complexity of the process. QA approved the requested extensions. Documentation in this problem now includes the DCSC CIS Donor Adverse Reactions team activities. The minutes from September 2010 cited in this observation are from the CIS team meetings. The minutes from meetings held in October 2010 include discussion of missing DRIRs and are attached to the issue in the Automated Problem Management System (APMS). Preliminary evidence suggested that regions were initiating and sending DRIRs to the DCSC, but that the DCSC did not receive the DRIRs or could not locate them. The investigation determined that the primary causes were associated with the inadequate communication between the regions and the DCSC regarding DRIRs and lack of reconciliation for DRIRs submitted by the regions.

As an immediate action and an interim measure to help ensure that DRIRs are received and managed at DCSC, the investigation team determined that an existing report from Red Cross data warehouse information providing a list of all donors registered in NBCS with X category complication codes would be a useful tool for DCSC supervisors. Since July 30, 2010, the DCSC supervisors have been using this report to reconcile the DRIRs. This activity was put into place as an interim measure until the CIS corrective actions are implemented.

Because of the process complexity and the multiple handoffs between regions and the DCSC, the team performed a comprehensive review of the process and completed a high level process map to identify inputs and outputs to the DRIR process. In July and August 2010, the team worked with the DCSC and regions to locate any missing DRIRs. The DCSC requested BDRs for all donors with X category complication codes with missing DRIRs so that new DRIRs could be generated to document donor follow-up attempts. On October 18, 2010, the team completed a detailed process map to identify potential gaps in the handoffs. Using the process map, the team identified potential failure modes to address the DRIR issues. Root cause analysis was completed in October 2010 and the team completed the CAP outlined in the CIS Plan, including specific corrective actions to address the failure modes identified during the investigation for problem E-0836426.

See the response to Observation 6 for additional details of the failure mode analysis and corrective actions developed to address missing DRIRs.

Observation 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 process verified, found six with no final quality review and six with no Medical Director review, as required by Form: Donor Reaction and Injury Record, 15.4frm015, v-1.2. Specifically,

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.

Response to Observation 6: (APMS # E-0900220)

This observation describes the investigator's concern regarding delays in the Medical Director review and the final quality review of the DRIR.

Red Cross acknowledges that there is a backlog of donor complications cases, initiated before July 1, 2010, that are pending final quality review of the DRIR and case closure. The CIS includes a detailed plan to complete the review of these cases. As of December 13, 2010, there were 296 open DRIR cases remaining in the Charlotte backlog and no open DRIR cases in Philadelphia backlog.

Response to Observation 6.A and 6.B
The final quality review of the five cases cited in this observation subsection was completed by October 4, 2010. One of the two cases listed as not having medical review, P201002051004o46, had Medical Director/designee review performed on September 29, 2010; however, it did not have final quality review. The final quality review was completed on October 5, 2010. Case P201002231258o37 had the Medical Director/designee review and final quality review completed on October 7, 2010.

Response to Observation 6.C
Since the final quality review is the final step in the process, the Medical director/designee review must be performed prior to and within the time period established for the final quality review. As clarification to this expectation, Temporary Authority TA 10-754 was released on December 14, 2010 to explicitly state that the Medical Director/designee review must also be completed within (b) (4) unless the Medical Director specifically requests additional follow-up that extends beyond this time.

The DCSC implemented local actions to improve the process for management of reports of Donor Adverse Reactions as described below. These actions demonstrated limited improvement. Corrective actions for the Donor Adverse Reaction CIS will also address timeliness of Medical Director/designee review and the final quality review.

Management of Donor Adverse Reactions and the Donor Reaction and Injury Record (DRIR)

Donor adverse reaction information is obtained from several sources including the DRIR initiated at the regional collection site, donor callbacks, and third party information. The process starts when a donor complication is documented at the collection site or reported to the DCSC, and ends when final review of the case is completed.

The DCSC manages DRIRs for all Red Cross regions with the exception of the Puerto Rico Region. The final quality review documented in Section 11 of the DRIR is an independent review of all entries to ensure all applicable actions have been completed and are accurate. A trained DCSC Operations staff person performs the final quality review of DRIRs managed by the DCSC.

The DCSC receives and investigates approximately 1400 DRIRs per month. The DCSC Donor Care Specialist (DCS) team has the primary responsibility for donor complication management. Critical steps associated with the DCSC process include:

(b) (4)

[redacted]

Actions Implemented to Address Timeliness of Review of the DRIR

Prior to this inspection, the DCSC took actions to address donor reactions and injury reports (DRIR) and missed timelines and increase overall process efficiency:

1. In November 2009, the DCSC implemented a specialized team structure, Donor Care Specialist Team, to ensure consistent quality care for donors by having a limited number of staff dedicated to managing donor reaction reports. The team approach was implemented in November 2009 and the Donor Care Specialist Team was fully staffed as of July 2010. Training of the newly hired staff was completed by the end of August 2010.
2. In February 2010, an (b) (4) database report was released listing the cases pending Medical Director and final quality review and is designed to assist staff in managing open cases.
3. In February 2010, the hard copy filing system for cases pending Medical Director and Final Quality Review was defined to help staff manage the workload. Cases are organized by the case initiation date.
4. On June 1, 2010, a Temporary Authority (TA) 10-696 against WI 14.3.178, *Final Donor Complication Review*, was implemented and defines a timeline for the final quality review for cases opened on or after June 1, 2010. This Temporary Authority states the, "final quality review must be completed within 3 months of the case being opened unless the Medical Director specifically requests additional follow-up that extends beyond this time. The Medical Director must document the request for a case to remain open on the DRIR or electronic equivalent."

[2] The (b) (4) database is used to track and manage workload associated with functions in the DCSC including donor complications.

5. On September 30, 2010, (b) (4) was implemented and includes a new report to track the length of time since the last donor follow up contact attempt. This report will help team leads and supervisors identify and track open cases until final quality review is complete.

Additionally, the DCSC management of donor reaction and injury documentation was determined to meet the criteria of a Significant Corrective Action (SCA). On May 3, 2010, BHQ filed the SCA with the FDA Baltimore District Office.

DRIR cases are monitored to ensure they are reviewed within (b) (4) of being opened as required by TA 10-696. If cases are not reviewed within the (b) (4) timeframes, problems will be logged and investigated. The DCSC has also increased the supervisory oversight and monitoring of these cases in order to continue improving adherence to the timeline.

In July 2010, DCSC hired additional dedicated staff to manage the DRIR workload and ensure timely evaluation and appropriate management of donor reactions. The DCSC Donor Adverse Reaction CIS team evaluation of the current DRIR process is described below.

<u>CIS Corrective Actions to Address Missing DRIRs and Lack of Timely Management of DRIRs</u>
Through process flow analysis, review of problem data, FDA 483 observations, and QA audit observations, the problem investigation team, along with CIS team members, identified seven failure modes for missing DRIRs that will be addressed by the CIS plan:

1. The DRIR was not sent by the region and the DCSC did not detect that it was missing
2. The DRIR was sent by the region but was not received by DCSC
3. The DRIR was received by the DCSC but not logged in the (b) (4) database
4. Donor follow up not performed by the DCSC in a timely manner
5. The DRIR was not forwarded for Regional MD/DCSC designee review in a timely manner
6. The DRIR was not reviewed by DCSC Case Investigator within (b) (4) of completion of investigation
7. The Final Quality Review was not performed within (b) (4)

The investigation team developed corrective actions to improve donor adverse reactions case file consistency, documentation, and management at the Charlotte and Philadelphia DCSC sites. The following corrective actions will be implemented.

1. Improve tracking of DRIRs by:
   - Establishing regional points of contact (POCs) for DRIRs to assist with resolution of discrepancies and improve communication for the hand-off of DRIRs from the regions to DCSC. Target December 31, 2010
   - Implementing NBCS Ad Hoc query "Donor Reactions by Registration Date". Supervisors will be responsible for ensuring a DRIR is received/ initiated in (b) (4) for each X complication code registered in NBCS. This query will replace the report from Red Cross' data warehouse described as an immediate action in the response to Observation 5. Target January 31, 2011

- Standardizing the process for submitting DRIRs to the DCSC through folders on a shared drive and establishing a process for regions to notify DCSC through the portal page when DRIRs are submitted. Target January 31, 2011

2. Decrease average cycle time from initiation of DRIR to closure by:
   - Developing and communicating to DRIR staff, regions, and Medical Directors guidelines for time frames to achieve key milestones in the process. Target December 31, 2010
   - Effectively and consistently use existing (b) (4) reports to monitor performance according to established time frames. February 28, 2011
   - Training all regional Medical Directors on the use of (b) (4) for DRIR review. Target April 30, 2011

These corrective actions will help ensure appropriate reconciliation of the receipt of incoming DRIRs as well as timely management of DRIRs including the Medical Director and final quality reviews. All corrective actions are targeted to be completed by June 2011.

Problem Management – Management of Suspect Blood Products:

Observation 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 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-001219-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 on 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.***

Response to Observation 7: (APMS # E-0900232)

An evaluation of all problems referenced in this observation was completed and the main issues with managing the problems have been identified as:

- Failure to triage incoming work and to assign ownership of problems in a timely manner
- CAP was not developed within thirty days/multiple extension for high risk problems
- Lack of complete and appropriate mapping of failure mode/root causes/corrective actions/effectiveness checks
- Problems not linked appropriately in the Automated Problem Management System (APMS)
- Corrective actions and effectiveness checks not performed by approved due date
- Inadequate QA review/ QA approved extension requests without sound rationale

These failure modes are included in those identified during the Root Cause Analysis performed for the CIS for PM and QA. Please refer to the corrective actions outlined in the response to Observation 3 above. The actions being taken under the CIS should help the PM staff avoid these types of errors when managing problems and trends in the future. In addition, the assistance being provided by other Divisions will help ensure timely triage and management of problems until the DCSC PM department is operating efficiently and can be self-sufficient in managing the incoming workload.

Management of Suspect Products

DCSC management of suspect products is undergoing a focused effort through the Component Retrieval CIS Plan. The Component Retrieval CIS team, comprised of DCSC operational staff and management, a BHQ principal investigator, a Lean engineer, as well as manufacturing management, Problem Management and QA staff, completed a failure mode and root cause analysis on October 30, 2010. The team focused on the failure mode "Hold/Property Not Applied" as this accounts for approximately [redacted]% of the problems occurring at the DCSC from September 2009 through July 2010. The identified potential root causes are:

- Staff are unclear when a hold should be applied because there are many scenarios that are unique and require different actions. Some examples are the expiration dates of manufactured products and a misinterpretation of what the product status "ended" means in the National Biomedical Computer System (NBCS).
- Reconciliation of incoming work is inadequate to ensure that all regional requests are received and managed.
- Staffing levels are insufficient to manage the workload.
- DCSC staff may misinterpret information provided on documents received from the region, which may lead staff to follow an incorrect process.

Based on the investigation by the CIS team, the DCSC is planning the following actions to improve performance. Target dates for implementation of these actions will be established when the Component Retrieval CIS plan is finalized by January 31, 2011.

- Assessing appropriate staffing levels and hiring where needed to add capacity.
- Implementing a SWAT team to work on the large gain control efforts with team members on each shift.
- Revising WI 14.3.183, *Providing Documents to the Donor and Client Support Center*, to incorporate regional documentation of retrieval categories that match the DCSC web-based communication tool to aid DCSC staff in following the appropriate retrieval guidance.
- Developing practice session/training material for line staff regarding unique scenarios for appropriately applying hold properties and the resulting impact on consignee notification/suspect product management.

The effectiveness of these changes will be measured under the criteria outlined in the Component Retrieval CIS plan.

Problem Management – Confirmatory Test Results and the DDR:

Observation 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 on 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. 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.***

Response to Observation 8: (APMS # E-0900242)

An evaluation of all problems referenced in this observation was completed and the main issues with managing the problems have been identified as:

- Incomplete investigation of the problem
- CAP was not developed within thirty days
- Corrective actions and effectiveness checks not performed by approved due date
- Problem closed prior to completion of corrective actions and/or effectiveness checks
- Problems not linked appropriately in the APMS
- Inadequate QA review

These failure modes are included in those identified during the Root Cause Analysis performed for the CIS for PM and QA. Please refer to the corrective actions outlined in the response to Observation 3 above. The actions being taken under the CIS should help the PM staff avoid these types of errors when managing problems and trends in the future.

Response to Observation 8.B
Prior to the identification of the trend cited in this observation, DCSC operations requested the Donor Management Process and Instruction Design Director to develop and deliver a workshop to staff who enter and verify confirmatory test results and retrieve product based on those test results to enhance knowledge of the process. This workshop, *Test Result Retrievals*, [see exhibit IX] was delivered in October and November 2009 to the identified staff. Following implementation of the functionalized structure, periodic team meetings continue to reinforce this knowledge.

Staff are trained and released to task based on the standard training assessment tool and DCSC management believed the staff were appropriately trained and understood their tasks. However, DCSC management acknowledge that staff need additional experience and exposure to a variety of scenarios in order to become proficient in tasks. As described in the *FDA Form 483 General Response*, a CIS sub-plan has been developed to improve training and training will be an area of focus in the MCIS.

Donor Management and Management of Confirmatory Results

The DCSC had previously identified problems with timely management of confirmatory test results. These test results must be entered into NBCS within two business days of receipt in accordance with WI 14.3.101, *Finalizing Test Results*. The DCSC had taken or planned to take the following actions prior to this inspection:

- By March 26, 2010, the DCSC implemented revised WI 14.3.101, *Finalizing Test Results*, v-1.3 that now contains information for the Clarify case priority type to use. [See Exhibit X]
- By September 20, 2010, the DCSC Charlotte facility assigned (b) (4) Donor Counselors to monitor and receive test result-related calls. In addition, (b) (4) trained regional staff have been assigned as a temporary measure to enter and verify test results for the DCSC.
- Effective September 21, 2010, the Donor Counselor lead staff run an additional NBCS report (Donors by Assertion Report) each (b) (4) to identify donors with positive test results for reconciliation purposes. The staff will continue to run this report until the reorganization initiative is deemed effective.
- By September 27, 2010, the DCSC completed the reorganization of activities based on Functional Areas/Specialization. The Donor Notification Specialist teams are responsible for managing all test result-related activities that include obtaining test results, distributing test results, entering and verifying test results in NBCS, and monitoring timely receipt of test results.
- By November 1, 2010, the DCSC hired (b) (4) additional Donor Counselors and (b) (4) Donor Notification Specialist in the Philadelphia facility.

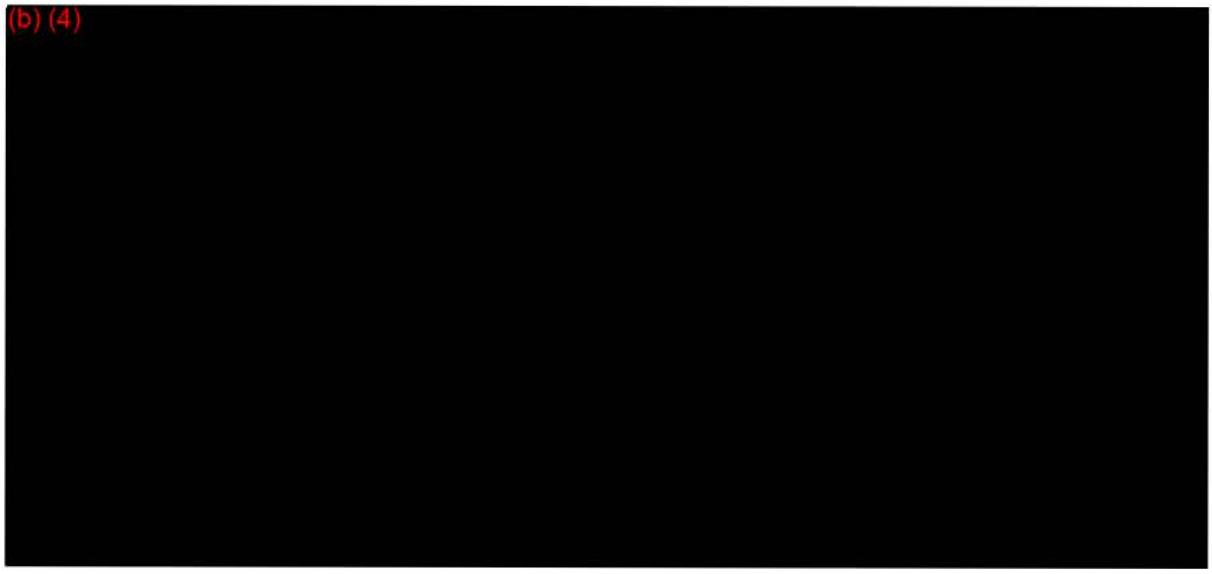
The Donor Management CIS team evaluated the DCSC issue related to confirmatory test result management and performed a failure mode and root cause analysis that was completed on November 8, 2010. The cross-functional team's review of problems discovered in March through May 2010 determined that the predominant failure mode was "late entry of confirmatory results" and identified the following as potential root causes for that failure mode:

- Clerical staff may not understand the importance of the results and entry into NBCS in a timely manner. The clerical staff person may fail to print the reports or may place the printed reports on counselor's desk/chair resulting in delayed management of the results if the counselor is working an alternate shift or is on leave.
- Staffing shortages may cause staff to rush to keep up with the workload resulting in errors due to process short cuts and failure to adequately review their own work.
- Clerical staff may fail to follow up with the Confirmatory Lab for late or missing confirmatory test results.
- Communication to next shift is insufficient in conveying that there is a request for a change to a database pending regarding test result management.
- Confirmatory test results are reported to DCSC in various formats.
- DCSC staff are confused as to what priority level to use when opening cases in the (b) (4) System requesting changes to a database.

The team mapped each of these potential root causes to the implemented actions described above and determined that no additional corrective actions will be developed at this time.

The DCSC will continue to assess staffing levels and will hire additional staff when needed to maintain capacity with adequate numbers of staff. Notable improvement in managing test results in a timely manner has been realized since these changes were implemented as evidenced by the chart below. The effectiveness of these changes will be measured under the criteria outlined in the Donor Management CIS plan.

(b) (4)



Observation 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[3] 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 site in 9/10, but not documented in I-0020096-FC as of 10/1/10. The status of the work flow revisions is [sic] 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.***

Response to Observation 9: (APMS # E-0900255)

An evaluation of all problems referenced in this observation was completed and the main issues with managing the problems have been identified as:

- CAP was not developed within thirty days/ Ineffective proactive monitoring of Level 2/3 problems requiring a CAP/ Multiple extension for high risk problems
- Incomplete investigation of the problem
- Problems not linked appropriately in the APMS
- Corrective actions and effectiveness checks not performed by approved due date
- Inadequate QA review/ QA approved extension requests without sound rationale

These failure modes are included in those identified during the Root Cause Analysis performed for the CIS for PM and QA. Please refer to the corrective actions outlined in the response to

[3] The BPD code for problem E-0664458 is MI-00-01-19, not MI-00-01-09 as cited in this observation.

Observation 3 above. The actions being taken under the CIS should help the PM staff avoid these types of errors when managing problems and trends in the future.

Late Consignee Notification (48-hour notification and follow-up letters)
BHQ was investigating problems with consignee notifications in systemic trend E-0382438 and in May 2009, the EC for the trend indicated that the CAP was ineffective. The data reviewed for the EC indicated that the DCSC was the major contributor to the problems during the EC monitoring period. The CAP was modified to focus corrective actions on the DCSC operations. The DCSC implemented multiple corrective actions; however, on August 23, 2010, the modified CAP was deemed ineffective based on the data reviewed for the sustained EC.

Issue I-0000511-EFC was opened on September 20, 2010 to develop a new CAP focused on the DCSC operations. The baseline data from that investigation shows late 48-hour notifications to the consignee as the predominant failure mode for both DCSC locations, accounting for [redacted]% of the problems.

Additionally and independent of the systemic trend investigation, the DCSC initiated a Six Sigma Black Belt project, in February 2010, with a Lean engineer to look for ways to streamline the consignee notification process at the DCSC. The work and corrective actions from the Black Belt project are documented in problem E-0664458. The DCSC implemented corrective actions including the consolidation of activities for functional area (functionalization) in the fall of 2010. The work and other planned corrective actions from the Black Belt Project were evaluated during the CIS team review and during investigation of a BHQ Systemic Trend as described below.

The cross-functional Component Retrieval CIS team included the baseline data from the systemic trend and the Black Belt project analysis in the failure mode and root cause analysis to identify the following potential root causes of late 48-hour consignee notifications. This analysis was completed on November 8, 2010.

- Staff assigned to perform component retrieval functions do not perform a self-review or perform an insufficient self-review of their work because of distractions, high work volume, phone interruptions, and/or do not use the appropriate source document for review.
- There is no formal reconciliation of the DCSC incoming work.
- There are many handoffs of work from one staff person to another; one staff person does not manage a retrieval case from beginning to end.
- Handoffs between shifts are poorly defined with little prioritization of work
- There is no procedure to explain the appropriate hand off from regional staff to the DCSC for component retrieval; handoffs between region and DCSC are not documented.
- Regions do not provide component retrieval information to the DCSC in a consistent format.

The DCSC has taken the following actions:

- By May 31, 2010, established a team of staff to answer incoming calls related to eligibility questions to reduce distractions and phone interruptions.

- In June 2010 (Philadelphia facility) and September 2010 (Charlotte facility), implemented teams based on functional/specialized responsibilities. The Donor and Client Support Specialist (DCSS) Teams have primary responsibility to manage donor eligibility calls, donor reinstatement calls, and component retrievals.
- In August 2010, the DCSC initiated a review of key cases within (b) (4) hours of receipt to verify that all critical and time-sensitive tasks had been completed. This review was performed (b) (4) . In November, the DCSC extended the review (b) (4) (b) (4) , but focused the review on Component Status Change Records (CSCRs) to ensure that all indate products had been appropriately controlled. This review will continue until all CIS corrective actions are implemented and the data show that they were effective in appropriately notifying consignees.

The DCSC will take the following additional actions. Target dates for implementation are not provided for the last two actions and will be established when the Component Retrieval CIS plan is finalized by January 31, 2011.

- Assess staffing and hire where needed to add capacity and sufficient staff. Target December 30, 2010
- Improve the current "Shift handoff" process to identify work to be done by a subsequent shift, including retrievals in process and prioritization of remaining work. Target February 28, 2011
- Implement a SWAT team to work on the large gain control (team members on each shift).
- Standardize regional/DCSC communication. The DCSC will design a plan for standardization of communication between the regions and the DCSC.

Since some of the corrective actions were recently completed and others are pending implementation, the effectiveness of these changes in improving the timely notification of consignees will be measured under the criteria outlined in the Component Retrieval CIS plan. In addition, management of consignee notification and component retrieval will be reviewed as part of the metrics included in the enhanced DCSC Dashboard that will be available by December 20, 2010. These metrics will be reviewed during the (b) (4) status calls with senior leadership.

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

Observation 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.

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 notification 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.

Response to Observation 10: (APMS # E-0900278)

Upon investigation of this observation, the DCSC determined that corrective actions for the SCA submitted to FDA on July 22, 2010 were developed and documented under problem E-0819626/I-0020742-FC. The problem referenced in this observation (Exception E-0822345 with an SCA reporting issue I-0011107-NF) was used only to document the reporting of the SCA to FDA. The investigation of this observation identified that the problem manager did not add a reference to problem E-0822345 indicating that the corrective action for this SCA was managed under problem E-0819626. This documentation has been corrected. The Problem Management CIS plan will address the DCSC failure to manage SCA problems in accordance with System 10, *Problem Management*, procedures.

The DCSC performed a retrospective review of cases requiring health department notifications. As this review identified several cases in both DCSC locations for which the required notification had not been performed, Red Cross submitted the SCA cited in this observation. The retrospective review of these cases was completed by July 30, 2010. Although the CAP for this problem was documented in issue I-0020742-FC, the additional required health department notifications identified during the retrospective review were not monitored and had not been performed.

As of September 28, 2010, all required state health department notifications identified during the retrospective review were completed for all confirmed positive infectious disease markers. Corrective actions developed for the failure to notify local or state health departments include addition of a note to the donor file in NBCS when the notification is complete. To monitor the effectiveness of this action, DCSC management staff have incorporated the review of routine donor assertion queries from NBCS into their management oversight processes. No problems have been logged for failure to perform health department notification within the required timeframe from August through November 2010.

Management of the National Donor Deferral Registry (NDDR) and Problem Management Associated with the NDDR:
Observation 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, 2001. 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.

Response to Observation 11: (APMS # E-0900294)

The DCSC and regional facilities follow processes outlined in documents under the Directive, 14.2.014, *Management of the National Donor Deferral Register*. With the transition of the NDDR donor management activities to the DCSC, three DCSC staff were trained on the BHQ local documents for managing the consolidated Donor File Check list, searching NDDR, and performing NDDR effectiveness check. The BHQ local procedures remained active during the transition of NDDR activities from the regions to the DCSC. Development of new NDDR documents began in March 2010 and these documents were released to the field under Transmittal Sheet 6225 on October 28, 2010. [See Exhibit XI] By December 13, 2010, the new NDDR procedures were implemented and the local BHQ NDDR documents were made obsolete.

Observation 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 #s (b) (6) and (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.

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 test results not performed, confirmatory test results not entered and test results not 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.***

Response to Observation 12: (APMS # E-0900307)

This observation contains two concerns: 1) Inadequate or untimely management of problem investigations related to management of confirmatory results and 2) Late NDDR entry due to untimely management of confirmatory test results causing a Donor File Check to be performed.

An evaluation of all problems referenced in this observation was completed and the main issues with managing the problems have been identified as:

- CAP was not developed within thirty days/ Multiple extension for high risk problems
- Incomplete investigation of the problem
- Lack of complete and appropriate mapping of failure mode/root causes/corrective actions/effectiveness checks
- Problems not linked appropriately in the APMS
- Corrective actions and effectiveness checks not performed by approved due date
- Inadequate QA review/ Untimely QA approval of extension requests

These failure modes are encompassed by those identified during the Root Cause Analysis performed for the CIS for PM and QA. Please refer to the corrective actions outlined in the response to Observation 3 above. The actions being taken under the CIS should help the PM staff avoid these types of errors when managing problems and trends in the future. In addition, the assistance being provided by other Divisions will help ensure timely triage and management of problems until the DCSC PM department is operating efficiently and can be self-sufficient in managing the incoming workload.

Late National Donor Deferral Register (NDDR) Entry

In November 2010, the DCSC discovered that a late test result entry caused a Donor File Check (DFC) to be required. The late test result entry occurred in the Charlotte DCSC in July, 2010, prior to creating the Donor Notification Specialist Team in the Charlotte DCSC. There have been no additional occurrences since this team was established.

See the response to Observation 8 above for details of the failure mode analysis and corrective actions developed to address late confirmatory test result entry.

Recipient Complications and Associated Problem Management Issues:

Observation 13:

Job Aid 11.4ja056, 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, JA11.4ja056 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 11/4/09 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 that 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 12/18/09 and closed 5/25/10, a total of 158 days, did not have 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.***

Response to Observation 13: (APMS # E-0900332)

The three recipient complication cases cited in this observation were open longer than 90 days and were closed prior to the start of this inspection.

- Case ID DCSC-P-053-TR-TRL00375 remained open awaiting donor's availability to provide a follow-up sample.
- Case ID DCSC-P-053-TTI-HBV00429 remained open because of difficulty with contacting and scheduling the donors involved for follow-up samples.

- Case ID DCSC-P-053-TTI-HBV00651 remained open to allow the required six months from collection of the suspect donation to elapse prior to donor follow-up testing.

Each of the three cases had valid reasons for remaining open greater than (b) (4) days, although, as cited in the observation, there were no monthly updates after the 90 days explaining these reasons. The DCSC CIS plan for recipient complication includes corrective action for late or missing documentation in recipient complication cases.

On November 9, 2010, the DCSC Executive Medical Officer discussed the following issues on the Case Investigators' monthly conference call [See Exhibit XII]:

1. Philadelphia DCSC FDA 483 observations related to recipient complications and missing documentation in cases remaining open greater than 90 days.
2. The requirement to document the reason for cases remaining open longer than 90 days per 11.4.ja056, *Timing Guidelines for Recipient Complication Investigations*, in the case notes section of checklist 11.3.ck003, *Recipient Complication Checklist*, as well as the requirement to document a (b) (4) review thereafter until closure.

On November 12, 2010, the DCSC Executive Medical Officer notified all case investigators and regional Medical Directors of the expectation to meet at least (b) (4) to update the status of open recipient complication cases [See Exhibit XIII].

Observation 14:

The DCSC has yet to implement an effective corrective 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 [sic] with their staff the open cases report generated from the (b) (4) Lookback Log" and "Operations Staff of the involved Supervisors may not have been trained to generate and use reports in the Lookback log database." 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.

Response to Observation 14: (APMS # E-0900341)

An evaluation of all problems referenced in this observation was completed and the primary Problem Management issues are:

- CAP was not developed within thirty days
- Multiple extension for high risk problems/ Lack of expediency in development of CAs

These failure modes are included in those identified during the Root Cause Analysis performed for the CIS for PM and QA. Please refer to the corrective actions outlined in the response to Observation 3 above. The actions being taken under the CIS should help the PM staff avoid these types of errors when managing problems and trends in the future. In addition, the assistance being provided by other Divisions will help ensure timely triage and management of problems until the DCSC PM department is in operating efficiently and can be self-sufficient in managing the incoming workload.

Seventeen exceptions for occurrences of lookback cases not closed in a timely manner, discovered between March 15 and May 22, 2010, are attached to issue I-0019746-FC. The investigation team met on May 24, 2010 to identify the root causes. The team developed the CAP, which was sent to QA for approval on June 2, 2010. QA approved the CAP on June 14, 2010. On June 24, 2020, the Problem Manager reopened the CAP and updated the corrective action to clearly state the use of the reports from the Lookback Case Log to monitor lookback cases is required and, on June 25, 2010, QA approved the revised CAP. Corrective actions were implemented in July 2010 and an interim EC was completed on September 9, 2010. The actions taken to-date have been determined to be effective. A sustained EC is scheduled to be completed by December 20, 2010.

The DCSC data met trend condition criteria for problems discovered in the months of May and July 2010 for this category of problems. The corrective actions taken for I-0019746-FC were to ensure that all staff knew how to use the lookback log and that pending work for lookback cases was reviewed on a routine basis. The corrective actions were in full effect by the end of July 2010.

The two trends cited in Observation 14.B and 14.C were reviewed by a BHQ Problem Investigations Director. Trend E-0831094 was identified in June 2010 from data for May 2010 and trend E-0864242 was identified in August 2010 from data for July 2010. The problems in the baseline for each trend were determined to be the same root cause and occurred prior to full implementation of the corrective actions developed in problem I-0019746-FC. These trends were appropriately attached to No-Formal-CAP issues (NF), in accordance with 10.4.ja031, *Appropriate Use of No Formal CAP Issue Types*, since the problems occurred prior to full implementation of corrective actions.

Health History Deferrals and Associated Problem Management Issues:
Observation 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.)

Response to Observation 15: (APMS # E-0900351)

This observation contains two concerns: 1.) Adequate controls are not in place to ensure that health history reports are generated daily and 2.) Draft documents are in use.

Adequate controls are not in place to ensure all deferral records are received
The DCSC is responsible for processing blood donor deferrals to determine if previous donations require retrieval. In addition, the DCSC initiates Biological Product Deviation Report (BPDR) submissions to FDA when required. The DCSC staff perform this activity by using the Health History Deferral (HHD) Report and copies of the Blood Donation Records (BDRs) from

deferred donors. The HHD Report is generated from the National Biomedical Computer System (NBCS) after the regions enter the donor deferrals into NBCS from the BDRs and lists donors deferred each day by region. The DCSC staff person submits the HHD Report and the deferral BDRs to the supervisor/lead. The supervisor/lead verifies each HDD was reviewed and ensures staff are assigned to manage the donor deferrals and retrieval actions, as applicable.

On September 8, 2010 during the FDA inspection at the Philadelphia DCSC, the FDA requested all July HHD Reports for three of the ten regions serviced by the Philadelphia DCSC. One report from July 8, 2010, requiring product retrieval and BPDR submission, had not been processed. Both required activities were completed on September 8, 2010. On September 9, 2010, the DCSC logged problem E-0869169 to investigate and determine the scope of the problem.

Following this discovery by the FDA investigator, DCSC Management requested a review of all of July and August reports completed by the Philadelphia DCSC. The review identified three additional reports not processed from July. All reports from August had been processed. Of the three reports not processed from July, one deferral from July 10, 2010 required a market withdrawal. The DCSC investigation of these omissions identified that one interim supervisor was responsible for verifying that Health History Deferral reports had been processed.

DCSC Management extended the review of all HHD Reports for the Philadelphia location to include dates March 1, 2010 through September14, 2010. This review was completed September 16, 2010. Seven reports, including the one listed above, were identified as requiring actions:

- Three required BPDR submissions that were submitted on September 28, 2010
- Four required both product retrieval and BPDR submissions; all four were completed between September 8 and September 28, 2010

On September 8, 2010, DCSC Management requested a review of a sampling of HHD Reports from the Charlotte location. The sampling covered 13 days between June 24, 2010 and August 26, 2010 to ensure all shifts, teams, and days of the week were sampled. The review identified two reports requiring action. When these were discovered during the review, the reports were promptly processed by the overnight shift:

- One required a BPDR submission that was submitted on September 17, 2010.
- One required both product retrieval and BPDR submission; both actions were completed by September 22, 2010.

The investigation of these two reports identified that they both occurred on the overnight shift at the Charlotte location. The record review in the Charlotte location was extended to include the nine regions managed by the Charlotte overnight shift and was completed on November 16, 2010. The review included records from July 30, 2010 through September 16, 2010 and identified five reports that required both product retrieval and BPDR submission; both actions were completed for the five reports by November 17, 2010. This problem was determined to meet the criteria of a SCA on September 14, 2010 and the initial notification I-0011430-NF was sent to FDA on September 30, 2010.

By October 2010, as an immediate action, DCSC Supervisors/Leads track receipt of deferral BDRs from all regions by collection day to help ensure all deferral processing is complete each day for all regions. The Senior Director of Operations reviews the information from deferrals for each collection day to verify that all deferrals were completed for each region within the expected timeframe.

A new NBCS query, currently under development, will provide deferral information for deferred donors from all regions and will include Whole Blood Number (WBN) and last donation date for each deferred donor. This report will allow staff to quickly identify donors with prior donations and facilitate any required market withdrawal. This enhanced report will replace the multiple health history reports (one per region) currently used. All required information will be listed on a single report and will help staff identify deferrals requiring investigation for components within the risk period. The anticipated implementation date of the new enhanced report is January 2011.

Draft documents are in use

The DCSC used draft work tools during the transition of regional donor management activities to DCSC. In March 2010, the DCSC initiated Document Change Request (DCR) 10672 to finalize and release workflows according to System 3, *Policy and Procedure Management*, requirements. The draft process flow cited in this observation was finalized and on September 27, 2010, the DCSC implemented the approved process flow as 14.4.zflw004 W1670, *Deferrals* [See Exhibit XIV] under Transmittal Sheet 0129 W1670. At the same time, the DCSC implemented eight additional process flows under Transmittal Sheet 0129 W1670. [See Exhibit XV]

Observation 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.

Response to Observation 16: (APMS # E-0900375)

An evaluation of all problems referenced in this observation was completed and the primary Problem Management issues are:

- Incomplete investigation of the problem
- Corrective actions and effectiveness checks were not performed by approved due date
- Lack of complete and appropriate mapping of failure mode/root causes/corrective actions/effectiveness checks
- Inadequate QA review

These failure modes are included in those identified during the Root Cause Analysis performed for the CIS for PM and QA. Please refer to the corrective actions outlined in the response to Observation 3 above. The actions being taken under the CIS should help the PM staff avoid these types of errors when managing problems and trends in the future. In addition, the assistance being provided by other Divisions will help ensure timely triage and management of problems until the DCSC PM department is operating efficiently and can be self-sufficient in managing the incoming workload.

Refer to the response to Observation 7 above for actions taken by the DCSC to address issues associated with mismanagement of suspect products and the Component Retrieval CIS.

Problem Management – Missed Timeframes:

Observation 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, know as SmartCAPA, was requested on 9/22/10 and revealed the following:

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 components	*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 problems not performed within five business days of receipt in QA	*System 10*	*8*
Development of CAP/approval of CAP not timely	*System 10*	*1*

Response to Observation 17: (b) (4) E-0900447)

The Red Cross acknowledges that the DCSC has not complied with the System 10, *Problem Management*, timelines and CFR/Consent Decree reporting requirements. Red Cross senior leadership directed that the CIS be developed and executed in multiple areas, including Problem Management, Quality Assurance, and Component Retrieval. The corrective actions defined in the CIS plan are focused on meeting System 10 timelines and CFR and Consent Decree reporting requirements.

As noted in the response to Observation 3 above, staff from Red Cross Divisions have been providing problem management assistance to the DCSC since the summer of 2010. Red Cross will continue monitoring the DCSC progress in meeting required timelines through the (b) (4) DCSC Dashboard and the Quality and Compliance Oversight Committee as corrective actions for the various CIS plans are implemented.

Problems related to late (b) (4) consignee notification are being addressed in the Component Retrieval CIS and corrective actions are detailed in the response to Observation 9 above. The remaining problem management timelines will be addressed in the corrective actions developed by the Problem Management and Quality Assurance CIS team as described in the response to Observation 3 above.

In addition to the actions described in the response to Observation 3, the specific area of concern for "Problems logged into SmartCAPA greater than five days after discovery" cited in this observation with 193 instances is under investigation in the BHQ Systemic Trend E-0553375.

The highest percentage of late logged problems are associated with Post Donation Information (PDI) events. The investigation team will be identifying the failure modes surrounding the deferral BDRs entry process and management of PDI as it relates to the potential for delays in entry of PDI problems into SmartCAPA.