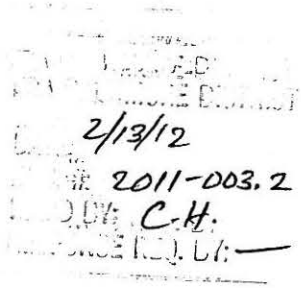
Decree Correspondence Contains Sensitive Proprietary Information
Provided Under Consent Decree Entered Under U.S. V American Red Cross
U.S.D.C., D.C. 93 CIV. 0949
102222

American Red Cross

Biomedical Services
2025 E Street, NW
Washington, DC 20006

February 13, 2012



Ms. Evelyn Bonnin
District Director
Baltimore District
Food and Drug Administration
6000 Metro Drive, Suite 101
Baltimore, MD 21215

Re: Adverse Determination Letter dated January 13, 2012

Dear Ms. Bonnin:

This letter responds to the concerns raised in the Food and Drug Administration (FDA) Adverse Determination Letter (ADL) dated January 13, 2012. The ADL relates to deficiencies associated with several 2010 FDA inspections of Red Cross facilities, particularly the FDA inspection conducted between September 2, 2010 and October 29, 2010 at the Red Cross' Donor and Client Support Center (DCSC) in Philadelphia, Pennsylvania. In accordance with Paragraph IX.A of the Amended Consent Decree, Red Cross hereby notifies the FDA that Red Cross will not dispute the adverse determination or the fine.

I have thoroughly reviewed the ADL and confirm to you that Red Cross senior leadership is committed to ensuring that all necessary changes are made to our blood service operations. Red Cross and Biomedical Services Headquarters (BHQ) management have every intention of fulfilling Red Cross' legal obligations and coming into compliance with applicable statutes, regulations, and the Amended Consent Decree. Red Cross' goal is to achieve and maintain compliance, ensure donor safety, and provide the safest possible blood components to the patients we serve.

Red Cross takes the ADL concerns seriously and is committed to comply with all FDA and Red Cross requirements. Since the date of the inspections cited in the ADL, Red Cross has taken significant corrective actions to address these concerns. Several of the actions are comprehensive in nature and some actions are ongoing or yet to be completed. These actions, collectively, comprise the Red Cross ADL Compliance Plan (hereafter referred to as the "ADL Compliance Plan" or the "ADL Plan"), which is included in this response.

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This letter includes the following items in response to the ADL.

- Attachment 1 – Red Cross Response and ADL Compliance Plan
- Attachment 2 – Status of Responses and Requests for Extensions – this attachment provides FDA with a status report of the Red Cross' response to each FDA Order and will be updated and included in subsequent letters responding to this ADL.
- Attachment 3 – Response to 30 day Orders (Order 2, Order 10, Order 12, and Order 14).

If you have any questions regarding this submission, please contact my office at 202-303-5300.

Sincerely,

Kathryn J. Waldman for

J. Chris Hrouda
Executive Vice President
Biomedical Services

cc: Karen Midthun, M.D., Director, CBER
Mary Malarkey

Attachments:

Attachment 1 – Red Cross Response and ADL Compliance Plan
Attachment 2 – FDA Orders – Response Status Report
Attachment 3 – Response to 30 day Orders (Order 2, Order 10, Order 12, and Order 14)

Exhibits:

Exhibit 1 – DCSC Quality Process Reviews
Exhibit 2 – DCSC Compliance Improvement Strategy (CIS) memorandum
Exhibit 3 – DCSC Modified CIS (MCIS) memorandum
Exhibit 4 – DCSC MCIS Project Plan – Final
Exhibit 5 – DCSC Dashboard (01/19/2012)
Exhibit 6 – DCSC CIS and MCIS Monitoring Metrics – Final (01/25/2012)

ATTACHMENT 1

This response contains confidential commercial information and trade secrets that belong to the American Red Cross

RED CROSS RESPONSE AND ADL COMPLIANCE PLAN JANUARY 13, 2012 ADVERSE DETERMINATION LETTER (ADL)

Executive Summary and Overview

The ADL raises broad issues regarding Red Cross' compliance with the law, the Amended Consent Decree, and Red Cross' standard operating procedures (SOPs). Specifically, FDA identified issues in the following broad areas: (1) managerial control; (2) quality assurance (QA); (3) problem management; and (4) good manufacturing practice (GMP) violations. The FDA also identified issues with the National Donor Deferral Register (NDDR); these issues will be addressed in the responses to Orders 8 and 13.

The FDA-cited violations pertaining to managerial control and QA are primarily focused on Donor and Client Support Center (DCSC) related activities. The other cited violations related to problem management and adherence to GMPs, either pertain to the DCSC and/or activities at Red Cross regional facilities.

In the problem management area, FDA raised specific concerns regarding violations pertaining to, in part: (1) management of suspect blood products; (2) donor reaction/injury records (DRIRs); (3) confirmatory test results and the donor deferral register; (4) consignee notification; (5) lookback investigations; and (6) meeting established timeframes.

With regard to GMP violations, FDA cited violations pertaining to: (1) an inadequate system for the distribution or receipt of blood products; (2) failure to follow manufacturer's instructions; (3) failure to monitor and/or follow written procedures; (4) inadequate training and staffing levels; and (5) inadequate recordkeeping.

These violations are addressed in the Red Cross' Compliance Plan (hereafter referred to as the "ADL Compliance Plan" or the "ADL Plan"), which is set forth below.

Red Cross' ADL Compliance Plan

Red Cross takes the ADL concerns seriously and is committed to comply with all FDA and Red Cross requirements. Since the date of the inspections cited in the ADL, Red Cross has taken significant corrective actions to address these concerns. Several of the actions are comprehensive in nature; some actions are ongoing or yet to be completed. The ADL raises several broad issues regarding Red Cross' compliance. Each issue will be addressed in the ADL Compliance Plan.

1. Managerial Control

In both the FDA Form 483, issued to the DCSC on October 29, 2010, and the ADL, FDA raised a number of concerns regarding the managerial oversight at the DCSC. As stated in the DCSC 483 response, Biomedical Services Headquarters (BHQ) determined that the mechanisms used to provide oversight of the consolidation of donor management functions into the DCSC were inadequate. Since the response submission, BHQ has significantly improved its oversight of the DCSC as well as over other major initiatives.

DCSC

BHQ senior leadership has worked with DCSC leadership to improve managerial oversight through: ongoing oversight meetings; use of operational and quality metrics; BHQ senior leadership visits to the DCSC; changes to DCSC management; oversight of the plan to reduce the backlog of cases pending review; and initially placing the DCSC under a compliance improvement strategy (CIS) and subsequently under a modified compliance improvement strategy (MCIS). Each of these activities is described below.

BHQ senior leadership, including: the President and the Executive Vice President of Biomedical Services; the Senior Vice President of Quality and Regulatory Affairs; the Vice President and Deputy General Counsel; and the Vice President and Chief Compliance Officer, Biomedical Services, established b4 meetings with the DCSC leadership on October 25, 2010. The purpose of these meetings is to ensure that senior leadership is informed about ongoing issues, can provide guidance to DCSC management, sets clear expectations, and ensures all necessary resources are made available to address identified compliance issues. These meetings are ongoing, having transitioned to b4 in September 2011. During these meetings, DCSC operations and QA management provide updates on the status of open cases, staffing levels, problem numbers by type, specific problem areas (*e.g.*, suspect products, meeting timelines), and employee problem data. In addition, an auditor is stationed full-time at the DCSC; she reports on the outcome of her reviews from the previous b4 at each meeting with senior leadership. The role of the onsite auditor is described below in Section 2, Quality Assurance.

The DCSC underestimated the number of staff required to manage the consolidation of the donor management functions from all regions into two DCSC facilities. In addition, the staff turnover rate was higher than anticipated and the ratio of tenured to new staff was lower than expected. From July 2010 to December 2011, the DCSC added approximately (b)(4) new operational staff. All staff hired by July 2011 participated in the MCIS workshops. Staff hired after July 2011 have the benefit of using the MCIS developed scenarios during training and receive newsletters that help to reinforce key principles discussed during the MCIS. The number of QA and PM staff was also inadequate to manage the problem workload. Besides the leadership changes described below, QA and PM increased from (b)(4) staff in June 2009 to (b)(4) staff in January 2012. Additional details regarding the staffing plan are provided in the response to Order 2.

Clearly defined metrics have been established to monitor current DCSC Operations, remaining problems, and adherence to problem management SOPs. These metrics have been incorporated into the DCSC Dashboard and are reviewed at the b4 leadership meetings described above so as to monitor progress and identify areas requiring additional attention. The Dashboard

is posted with other performance Dashboards on a shared site for easy access by BHQ and DCSC leadership in order to facilitate ongoing monitoring of progress.

BHQ senior leadership has made several visits to both DCSC locations to communicate the critical nature of the DCSC functions, the potential impact to donor and recipient safety, the importance of compliance with Red Cross SOPs, and to demonstrate BHQ's commitment to and support of the DCSC. During these trips, BHQ senior leadership has met with DCSC management and staff in separate meetings to encourage open and frank discussions. The next visits are targeted to occur in the b4 [redacted] Senior leadership will continue its visits to the DCSC facilities as long as necessary.

As noted in the DCSC 483 response, DCSC managerial and QA oversight was not sufficient to ensure that the DCSC was operating in a state of control and in compliance. Changes in the DCSC management team were described in the response. In particular, the Vice President of Manufacturing, Kay Crull, assumed leadership of the DCSC, effective November 3, 2010 and her title was changed to the Vice President of Manufacturing and Donor Management. The Vice President of Manufacturing and Donor Management hired Ann Judd as the Executive Director, DCSC effective November 1, 2011. Ms. Judd was formerly the CEO of the Red Cross National Testing Laboratory in Charlotte, NC and is an experienced leader with a proven track record in both operations and compliance roles at the Red Cross. In her new role, Ms. Judd will oversee and manage staff, activities, and processes at the DCSC, consistent with all applicable regulations, and ensure that the facility operates with excellent quality and customer service. Changes were also made in QA management, which will be described below in Section 2, Quality Assurance.

On July 7, 2010, due to an increase in problems and the results of two internal audits in the spring of 2010, the BHQ Quality and Compliance Oversight Committee (QCOC) directed the DCSC to develop a Compliance Improvement Strategy (CIS). The CIS was submitted to the QCOC in August 2010 and, after several review cycles, the QCOC approved the CIS on September 30, 2010. Nine plans were developed to address problems in specific functional areas. All but one of the 198 action items have been completed; the one remaining item is the implementation of a software package to help manage incoming work sent via an email template from the regions. Implementation of this package is targeted for b4 [redacted]

One of the items for which a CIS plan was developed was for a backlog of approximately 18,000 cases that were pending a final review, which is called "process verification". The DCSC management team developed a plan to complete these pending reviews and eliminate the backlog. The progress made against the plan has been reviewed at each BHQ/DCSC leadership meeting. As of February 10, 2012, there were 60 cases or approximately 0.3% of the original 18,000 in the backlog still pending review. The remaining cases are generally the most difficult to review as they include multiple subcases or are the oldest. According to the current plan, this backlog will be eliminated by the end of b4 [redacted]

On January 14, 2011, based, in part, on the issues identified in the DCSC 483, BHQ placed the DCSC under an Modified Compliance Improvement Strategy (MCIS). BHQ recognized that, in addition to the corrective actions included in the CIS, the DCSC needed to focus on the broader underlying issues. The issues included management and staff assessments, additional staff training, and a strategic assessment of IT needs for the DCSC. The DCSC MCIS plan was

approved on March 11, 2011. Details regarding the status of all MCIS actions are provided in the response to Order 12. The monitoring period to evaluate the effectiveness of the MCIS began January 1, 2012.

System-wide Initiatives: Project Management

Since the implementation of BioArch Release 1 (R1), BHQ revised its approach within its Change Management System to have a tiered-approach to managing projects with each successive tier having progressively more control and oversight than the preceding tier. Major initiatives, like the DCSC implementation, will now have the highest defined level of oversight. This includes establishing governance structures, oversight mechanisms, metrics for monitoring performance prior to implementation, and formal readiness reviews for the major stages of project development and implementation. One project, called (b) (4), which was created to implement an updated Commercial Off-the-Shelf (COTS) version of (b) (4), was placed under the highest level of oversight. A full-time project director was hired on April 11, 2011 to manage the (b) (4) project. In addition, the Change Management Board reviewed all open projects to determine whether any other projects should be placed under the newly defined highest level of oversight. No other projects met the established criteria for the new level of oversight. The Change Management SOPs have been revised to incorporate these criteria and are now being reviewed by BHQ QA. The current target date is to release the revised SOPs to all operating units in b4

System-wide Initiatives: Employee Pursuit of Excellence

In order to ensure that supervisors were having discussions with their staff regarding performance problems, two Divisions developed a system for tracking problems by employee and set triggers that would require specific follow-up actions to be taken. BHQ identified this system as a best practice and created a task force to revise the system, as necessary, for implementation in all Biomedical Services facilities.

The program is a problem reduction initiative that uses problem tracking software to identify and track employee problems, increase management and staff awareness, and enhance accountability among employees by emphasizing the collaborative nature of the initiative. Additionally, the program is intended to identify high performers and analyze the key characteristics that lead to those staff members' success. The name of the initiative, Employee Pursuit of Excellence (EPoE), is meant to convey the positive intent of the program; the goal is to help staff improve their skills.

EPoE provides a mechanism for supervisors and managers to track data to communicate with staff members about their individual performance. They can provide appropriate feedback, counseling and recognition based on the data. It also provides key information to facility management that allows them to understand better the quality performance in the Region/Division, and identify areas of regulatory risk within the organization. BHQ senior leadership reviews a summary report b4 to ensure there is adequate field leadership engagement and that there are no adverse trends that require additional management attention.

System-wide Initiative: Data Analysis and Risk Assessment

Based in large part on the discussions held with the FDA over the past year and a half, Red Cross has enhanced its methods for analyzing data, comparing facility performance against facilities performing similar activities (*e.g.*, comparing a region's performance to other regions), and assessing and documenting the overall level of facility risk. More information regarding the metrics, analysis and documentation method is provided below in Section 2, Quality Assurance, under the *Improved Metrics* and *Compliance Analysis* sub-sections.

2. Quality Assurance (QA)

DCSC

The ADL raised a concern regarding the adequacy of BHQ and DCSC QA oversight of DCSC Operations and cited several examples including, but not limited to, the backlog of open cases, failure to perform required Quality Process Reviews, and multiple quality audit reports that cited untimely management of problems.

BHQ relied too heavily on the reports provided by DCSC Operations and QA management; DCSC QA management did not provide an independent assessment of DCSC Operations nor were there an adequate set of metrics to objectively evaluate the DCSC performance. Since the DCSC 483 was issued on October 29, 2010, the following changes to BHQ and DCSC QA leadership have been made.

- Kathy Waldman, who was appointed interim Senior Vice President, Quality and Regulatory Affairs (SVP, Q&RA) in July 2010, was hired into the permanent position in December 2010. The former SVP, Q&RA resigned to accept a position outside the Red Cross in July 2010.
- Julie Hall, who had been serving as the interim Senior Director of Quality (SDQ) for the DCSC since November 2010, was hired as the permanent SDQ in April 2011. The former SDQ is no longer employed by the Red Cross.
- Patti Ancharski, who had been serving as the interim Director of Problem Management for the DCSC since February 2011, was hired as the permanent director in July 2011. The former Director of Problem Management is now working in a non-managerial position in another Red Cross facility.

The new DCSC QA management team focused on completing the Quality Process Reviews that were pending for 2010, managing problems effectively and in a timely manner, and enhancing oversight of Operations through routine operations walkthroughs. In addition, the Quality Process Reviews for 2011 were completed on time, and the number of open problems has decreased from more than 1,800 to fewer than 300 or approximately an 85% decrease.

Although notable improvements have been made since November 2010, the QA and PM management team continue to focus on improving the overall QA/PM activities at both DCSC sites, with a concentrated focus on ensuring complete problem management documentation and meeting timelines.

In November 2011, BHQ's Compliance Department completed an internal audit of the Charlotte DCSC. The audit contained observations related to the Donor Eligibility System and the Quality Assurance System. The audit and status of corrective actions are discussed at the b4 [redacted] Senior Leadership meetings with DCSC (discussed above). The results of this audit and the corrective actions developed in response will be addressed in full in the response to Order 1, which will be submitted no later than 60 days from receipt of the ADL.

Improved Metrics

In July 2010, FDA and Red Cross established a working group to discuss, in part, the metrics/performance measures that Red Cross was using to track its efforts to protect the public health and its compliance with the Amended Consent Decree requirements, the Federal Food, Drug, and Cosmetic Act (the Act), FDA's regulations, and Red Cross' SOPs. FDA concluded that Red Cross could improve the metrics/performance measures it was using to track its compliance efforts. As a result of these meetings, Red Cross defined a set of refined metrics/performance measures that it is now using to evaluate better the state of compliance of each of its facilities. One of the fundamental changes was a shift from comparing facilities that performed similar functions (*e.g.*, regions that collect blood) to the average of those facilities - to comparing each facility to other individual facilities that perform similar functions. This approach allows for the identification of statistical outliers as well as facilities performing above a pre-established trigger used as an early warning mechanism. The working group also agreed that a combination of aggregate and individual facility data will be reviewed in upcoming b4 [redacted] meetings. This approach will provide Red Cross and FDA with a clearer picture of Red Cross' overall system performance and Red Cross' progress toward demonstrating sustained compliance.

Compliance Department

The Compliance Department was established in late January 2011 by the President, Biomedical Services, to strengthen Red Cross' ability to analyze quality metrics collectively, to assess, independently and objectively, the state of compliance for facilities and processes, to identify areas of risk that might not be realized at the facility level, and to report the assessment results to Operations, Q&RA, and senior leadership.

The position of Vice President of Compliance, Chief Compliance Officer (CCO) Biomedical Services was established to lead the department and reports directly to the President, Biomedical Services. Craig Mendelsohn, Vice President and Deputy General Counsel, served as interim CCO until August 2011 when Thomas Manor assumed the role.

The reporting structure establishes that the Compliance Department operates independently of Operations and Q&RA. Compliance staff members have direct and unrestricted access to all Biomedical Services facilities, personnel, information, documents and records, excluding confidential personnel records and non-regulated information. This allows the department to provide thorough, independent and objective assessments of Biomedical Services facilities' compliance performance and improvement.

The Compliance Department is responsible for the following functions: compliance analysis; compliance monitoring; and auditing, both internal and supplier. These functions are described briefly below.

Compliance Analysis

The Compliance Department is responsible for evaluating collectively multiple sources of data to assess each facility's compliance profile on a (b) (4) basis. A formal mechanism and integrated process for evaluating performance data, with defined triggers for increased oversight, has been established. The Compliance Template (hereafter referred to as the Template) was developed to provide an overall picture of each facility's compliance performance based on an analysis of these different data sources. The key and high risk metrics agreed to by the FDA and ARC Working Group have been incorporated into the Template along with FDA Inspection Results, Internal Audit Results, Quality Scorecard Results, and Employee Pursuit of Excellence data. A Template is completed for each facility. A full set of Templates is completed, analyzed, and reviewed on a (b) (4) basis; two sets of Templates have been generated to date, in September 2011 (b) (4)) and in November 2011 (b) (4) (b) (4)). The next Template set will be developed and distributed in (b) (4) (b) (4)

BHQ senior leadership review the Templates, and based on the results and level of risk identified, determine which facilities require additional oversight as well as the oversight mechanism to use, *e.g.*, senior leadership oversight, system QCOC, or division/functional area QCOC. The Template results are then reviewed with Operations and Quality leadership and posted on a shared site for facility leadership use.

Compliance Monitoring

The Compliance Department monitors and tracks the status of each commitment made in the Red Cross Compliance Plan. The status of each commitment is reviewed with the staff member responsible for the action on a regular basis. The status of these commitments is shared with BHQ senior leadership, the QCOC, and the Red Cross Board of Governors Quality and Regulatory Compliance Subcommittee.

Auditing

The audit group performs the internal quality audits of all Red Cross Biomedical facilities, including the annual routine audits, the focused problem management audits, and special audits requested by senior or executive leadership. In addition, the group is responsible for performing audits of suppliers as part of the overall supplier qualification process.

Onsite Auditor in DCSC

In fall 2010, a team, including an auditor and the two Directors, Quality Audits, was assigned to develop the role of the DCSC onsite auditor and define the activities to be performed; these activities subsequently began in October, 2010. A fulltime auditor, (b) (6) , was assigned to the DCSC in January 2011 to provide an independent assessment of the DCSC facilities; Ms. (b) (6) is based in Charlotte, but evaluates records from both facilities and travels to Philadelphia when necessary. She reviews and reports to BHQ executive leadership on the status of CIS action items and effectiveness checks for completed actions. Ms. (b) (6) conducts focused reviews as directed by BHQ senior leadership or as requested by DCSC leadership.

Changes in the QCOC

Prior to January 5, 2012, each member of the QCOC was responsible for evaluating assigned reports and reporting risks or concerns to the QCOC. This meant that the members had to have a certain level of technical knowledge and experience. When the Compliance Department implemented the changes to the processes for evaluating metrics and data sources, the QCOC was revamped. The membership was changed to include the senior leadership of Operations, QA, and Compliance. The QCOC is now co-chaired by the SVP, Q&RA and the VP & CCO, Biomedical Services. The Compliance Department is now responsible for analyzing the metrics and other data and presenting identified areas of risk to the QCOC. The QCOC charter was revised in December 2011 and approved on January 5, 2012.

These changes ensure that the leadership of Biomedical Services is well-informed, without the filter of facilities' management, and can provide the oversight and support necessary to achieve improvements in compliance. The first QCOC meeting since these changes were implemented was on January 5, 2012. The QCOC meets at least b4 [redacted] and focuses on updates to compliance data and on updates from each facility under QCOC oversight. Additional information regarding the QCOC and other mechanisms used to ensure that senior leadership are aware of potential risks as early as possible will be described in the response to Order 16.

3. Problem Management

DCSC

The ADL identified issues regarding untimely management of problems and inadequate corrective actions to prevent problems from recurring in the DCSC. Since the inspection ended in October 2010, the DCSC has taken significant corrective actions to improve its ability to manage problems in a timely and effective way. As noted above, the QA/PM management is new and staffing levels have nearly doubled. With the inception of the CIS in July 2010, BHQ problem investigators were assigned to several of the CIS teams to support the DCSC problem managers and help ensure effective problem solving. The QA/PM staff members were assessed during the period of September 2009 thru August 2010; however, since many of them were relatively new at the time of the assessment, BHQ reassessed them in April – August 2011. The results of the QA/PM re-assessment revealed that the staff performance had improved. The DCSC was encouraged to continue to improve the workload balance for the PM staff, to resolve the backlog of problems, and to continue to develop the PM staff's ability to conducting effective investigations and developing corrective actions & effectiveness checks. The DCSC was already aware of these issues and had already developed corrective actions, which were included in either the CIS or MCIS. All QA/PM staff participated in the core MCIS workshops, which included, for example, sessions on Problem Management, Managing Suspect Product, and Managing Donor Adverse Reactions.

Although some problems have recurred, there has been significant progress in reducing their number. Actions such as automation or eliminating an unnecessary or duplicative form are preventive actions designed to eliminate problems. However, many other actions will reduce, but not necessarily eliminate, problem occurrences as many tasks have at least some manual steps.

Problem solving is often an iterative process and the DCSC continues to work to further reduce their problem occurrences. From January 2011 to December 2011, there was more than a 70% decrease in the number of problems that occurred.

Other Problem Areas cited in the ADL

In addition to the broad actions taken to improve the DCSC's ability to effectively solve its problems in a timely manner, the DCSC and/or BHQ has taken actions to address the specific problem areas cited in the ADL. These problem areas are discussed further below.

Management of Suspect Blood Products
One of the DCSC CIS plans focused on improving the DCSC's management of suspect products. The majority of the problems were due to late consignee notifications of in-date products. The DCSC has taken several corrective actions including: increasing staffing levels; holding workshops on performing reviews to identify and appropriately manage suspect product; and providing timely feedback to supervisors and line staff. There has been more than an 85% reduction in the number of occurrences of late notifications to hospitals when comparing the last quarter of calendar year 2010 to the same quarter in 2011. In January 2012, a majority of the late notifications were for recovered plasma sent to (b) (4) On January 23, 2012, the DCSC implemented additional corrective action intended to address the timeliness of (b) (4) notification.

Donor Reaction/Injury Records (DRIRs)
The ADL cites issues with the timely and effective management of problems, by the DCSC and by BHQ, related to DRIRs. As noted above, the DCSC has taken several actions to improve its management of problems overall. With the implementation of BioArch R1, the DRIR form was replaced with the Donor Complication/Injury Report (DCIR), and staff had some difficulty learning how to complete the new form. In August 2011, the DCSC opened a trend. Corrective actions were focused on the fields that staff had the most difficulty completing. DCSC supervisors led workshops reviewing each section of the form with all staff who are trained on completing the DCIR. From August 2011 to December 2011, the total number of problems related to the DRIR/DCIR in regions and the DCSC has decreased by more than 40%.

The ADL raises a concern regarding Red Cross' established success criterion and its determination of the corrective action's effectiveness for a BHQ trend regarding DRIR documentation problems. BHQ system trend, I-000334-EFC, was created on June 23, 2009 to address documentation problems on the DRIR. In reviewing options for corrective actions, a decision was made not to make significant modifications to the DRIR form until after implementation of BioArch R1. Therefore, BHQ released a communication to the field as a corrective action. Since it was not a process change, the expectation for improvement was appropriately low and the results better than expected. Although Red Cross deemed this corrective action effective, it is not meant to imply that sufficient work had been done to address the problem completely. It only means that the corrective action performed to address the particular failure mode was effective.

There are many factors that must be considered when determining the percent improvement based on corrective actions. Problem solving is an iterative process whereby the failure modes may need to be addressed in sequential steps. The Problem Management Work Instructions

10.3.003, *Investigating Problems*; 10.3.004, *Developing Corrective Action Plans*; 10.3.015, *Developing and Performing Effectiveness Checks; and* 10.3.018 *Trend Identification by BHQ,* prescribe the process that must be followed once a trend is identified. The failure modes contribution to the cause of the problem and the strength and sustainability of the corrective action are key in developing the effectiveness check and success criteria. The problem manager must identify the corrective action that will address the specific failure mode; thereby identifying the percentage of improvement that can be expected when the corrective action is implemented.

Both the DCSC and BHQ currently have a trend open to identify additional corrective actions to improve performance further. Additional information will be provided in the response to Order 7.

The ADL also identified an issue regarding DRIRs that failed to reach the DCSC from the regions. On January 4, 2011, the DCSC implemented a DRIR/DCIR National Biomedical Computer System (NBCS) query to enhance the reconciliation process associated with receiving DRIR/DCIR from the regions. The process includes the following elements:

- (b) (4)
-
-
-

With the implementation of this process, DCSC is able to ensure that all DRIR/DCIR forms have been received.

Confirmatory Test Results and the Donor Deferral Register (DDR)
The ADL states that the DCSC had not promptly investigated, corrected and prevented problems related to management of confirmatory test results and DDR entry. The predominant failure mode was late entry of confirmatory results; per DCSC procedures, these results must be entered into the NBCS withi(b) (4)business days of receipt at the DCSC. The DCSC implemented several corrective actions as part of the Donor Management CIS plan. As a result of these corrective actions, the monthly average of problems decreased from 5.2 to 0.7 when comparing July through December 2010 to the same time period in 2011.

Since the end of the FDA inspection in October 2010, one isolated staff performance incident has resulted in a donor file check. In March 2011, workflow changes were made to improve this manual process and the DCSC continues to evaluate any current problems for additional opportunities to minimize risk.

[1] (b) (4) is the software system used by the DCSC to create, manage, and document activity for different case types, *e.g.*, DSCR, CSCRs, etc.

Lookback Investigations
The ADL states that the DCSC did not promptly correct problems related to management of lookback cases. A majority of these problems occur due to a missed record review or a failure to initiate a case within b4 days of discovery. As performance problems are discovered, supervisors hold refresher classes with the involved staff member to review timeline requirements and to identify ways for the staff member to monitor his or her own work and complete the actions according to procedures.

In addition, a problem, I-0024079-FC, was initiated in May 2011. Corrective action included, in part: in-service sessions with staff; ensuring that the electronic Lookback log was monitored routinely; and adding a review of open Lookback cases to the management b4 meeting agenda.

The average number of problems per month for July – December 2011 was 2.5. This problem was closed as effective in October 2011.

Overweight Units
The ADL raises an issue regarding the management of a problem in the Heart of America Region. The Region did not consider problems where it was unable to determine the failure mode when determining whether the corrective action taken was effective. It is Red Cross' intent to include all relevant failure modes and any unknown failure modes when identifying the percentage of improvement. The Problem Management Work Instructions 10.3.004, *Developing Corrective Action Plans*, and 10.3.015, *Developing and Performing Effectiveness Checks,* prescribe the process that must be followed once a trend is identified, which includes developing the corrective actions and the effectiveness check criteria. The problem manager must identify the corrective action that will address the specific failure mode; thereby identifying the percentage of improvement that can be expected when the corrective action is implemented. This is considered the most conservative approach. The Heart of America Region did not comply with the intent of the PM procedures when determining the percentage of improvement for trend E-0717565. Once FDA made the Heart of America Region aware of the exclusion of this data, the Region opened a problem on August 16, 2010 to initiate a new trend investigation (I-0021272-FC); this trend was closed as successful on January 6, 2011. In addition, the Mid-America Division which includes Heart of America Region, communicated to the entire QA and PM department that all data must be evaluated when determining if the effectiveness check criteria has been met. Although there was nothing performed globally at the time this issue occurred, as a result of further investigation, Red Cross intends to highlight the process of designing effectiveness checks during a national problem management conference call in March 2012.

4. GMP Violations

Several of the GMP violations cited in the ADL, *e.g.*, failure to follow manufacturer's instructions for use of handwarmers, management of customer concerns, and lack of established timeframes for the Medical Director review of DRIRs/DCIRs, will be addressed in the responses to the associated orders. Others (of the GMP violations) relate to failure to follow SOPs and/or inadequate problem management, *e.g.*, the Heart of America Region did not initiate a DRIR to document a donor reaction and the care provided and the Connecticut Region did not provide a complete and accurate description in its notice of suspension. As described above, Red Cross has

implemented the EPoE program to ensure that staff members are provided with real-time feedback regarding their performance and given the support needed to improve their performance. Red Cross continues to develop its staff proficiency in effective problem solving through ongoing educational initiatives. Red Cross has also initiated a problem solving effort in the Collections area to evaluate why there are failures to follow procedures and why some of those failures go undetected. This effort is described immediately below.

National Collections Problem Solving Initiative

Red Cross monitors problem rates in all functional areas on a b4 basis. Historically, the Collections functional area contributes the largest percentage, approximately 72%, of the total problems. This is not surprising considering that the Collections department has the largest number of staff and many manual systems and processes.

Therefore, in September 2011, Red Cross defined a cross functional task force led by Tony Procaccio, Vice President Blood Collections and Kate Doerksen, Executive Director Problem Management, to investigate and address certain global problems in the collections area. The problem statements defined by the task force include:

- Front line collections staff do not consistently follow procedures as written
- Supervisory oversight of collection operations is not always effective in ensuring consistent compliance with regulations and ARC business practices

The task force used defined problem solving methods to conduct multiple root cause analysis sessions across the country. There were seven root cause sessions held in November and December 2011, involving staff representing 35 facilities across seven divisions. (b) (4) front line staff and (b) supervisors were interviewed. Problem solving tools, including brainstorming, affinity diagrams and causal trees, were used to identify and analyze probable causes. Data were gathered and used to verify the hypotheses. A smaller sub group of the task force met in person in January 2012 to brainstorm solutions.

This task force will present the results of the problem solving initiative and recommendations to American Red Cross Biomedical Services Senior leadership group in February 2012.

Other GMP Issues cited in the ADL

Other GMP issues that are not addressed in a response to an order nor related solely to failure to follow SOPs include:

1. Inadequate SOPs: Managing retrieval and/or consignee notification after the system for assigning unique numbers to pooled cryoprecipitate had changed. The MCIS in-services not only contained information specific to pool ID nomenclature and how to document actions appropriately related to pooled products, but also reinforced proper interpretation of the NBCS system tracking documentation when an initial product is "ended" to become part of a pooled product. Red Cross Job Aid, 11.4.ja067, *Communicating with Customers Regarding Pool ID Numbers*, describes the two different formats of the pool ID and provides an implementation date for each region. This job aid was originally implemented in December 2010 and a revised version 1.1

was implemented in January 2011. The MCIS in-service workshop referenced this job aid during the discussion.

2. Inadequate review: Missing consignee notification documentation and discrepancies between related documents. In September 2010, the DCSC implemented a structured file organization process that not only created a color scheme and labeling requirement for the different types of cases, but also provided a tool describing the expected contents of each case type. In addition to the case file structures, staff mentoring and coaching focused on performing quality self reviews, as well as documentation and timeline requirements in the procedures. During the MCIS in-service workshops, the instructors reinforced key information, such as: techniques for review; Component Status Change Request documentation; Donor Status Change Request documentation, and case file management.
3. Missing reconciliation process: Missing process to reconcile health history deferral reports daily. A reconciliation process including supervisor/leads tracking receipt of deferral BDRs from all regions by collection day was implemented in October 2010. In July 2011, Red Cross implemented a NBCS query which increased automated control in the process by replacing the multiple reports (one per region) previously needed to reconcile and process regional deferrals.

Summary

Red Cross has made significant improvement in its methods of analyzing data, identifying areas of risk, and reducing problems. Red Cross is seeking to ensure that the safest possible blood products are provided when needed by recipients and is fully committed to meeting all FDA standards to ensure compliance with FDA regulations and requirements.

Red Cross realizes that although there has been significant progress at the DCSC since the October 2010 inspection, there is still some additional work to complete. The facility continues to work on improvements, not only associated with individual tasks and processes, but also related to instilling a culture of quality and compliance. Examples of these initiatives include:

1. Increased compliance awareness of staff
    a. Developed MCIS Newsletters and Quality posters b4 [redacted] to focus all staff on the importance of their role in ensuring compliance.
    b. Posted bulletin boards with key metrics for DCSC Compliance goals.
    c. b4 [redacted] staff meetings with regulatory review by Quality and Operations Management.
2. Process Improvements
    a. Automated process was developed in key areas to reconcile incoming work (e.g., regional deferrals and donor adverse reactions).
    b. Competency assessments are now being performed by training/education department for independent evaluation of task performance.
    c. Strategic staffing calculator in use to ensure staffing is adequate for case load processing.

3. Improved regulatory oversight
    a. Robust QCOC [b4] meeting with DCSC (key) leadership including a focused review of key operations and quality metrics.
    b. Implemented an Employee Pursuit of Excellence Communications Tool that allows supervisors and managers to use problem tracking data to communicate with their staff members and improve their overall performance through objective and thorough review of problems.

In addition, Red Cross has improved its communication to all Biomedical Services staff regarding personal accountability through the EPoE program and ongoing compliance initiatives. For example, on January 23, 2012, Shaun Gilmore, the President of Biomedical Services, distributed a communication to all Biomedical Services staff members regarding the ADL. The communication stressed the progress Red Cross has made, the need for every employee to take personal responsibility for ensuring the quality of our products and services, and that we must do whatever is necessary to do our jobs correctly in order to achieve compliance.

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102238

ATTACHMENT 2

FDA Orders – Response Status Report

Order 1:
Within 60 days of receipt of this letter, provide a status report of each issue noted during internal audits of the DCSC since the beginning of consolidation in May 2008 and whether each issue has been effectively corrected. Please provide a justification for any open problems created as a result of an internal audit. Explain why they were not addressed promptly when the auditors found each issue.

Status: Red Cross will provide a response within 60 days of receipt of the ADL.

Order 2:
Within 30 days of receipt of this letter, provide a list and a complete description of each functional team in the DCSC, including a complete list of all supplemental sites assisting with Philadelphia and Charlotte DCSC activities. Provide a status report of the staff hiring plan described in your 12/15/10 response to the Philadelphia DCSC FDA 483 issued on 10/29/10.

Status: Red Cross' response is provided in this submission, dated February 13, 2012.

Order 3:
Within 90 days of receipt of this letter, re-examine the DCSC response to the ARC BHQ audit observations related to training. Report to FDA what ARC is doing to strengthen its DCSC training program given the audit observation and the lack of a corrective action plan to address training at that point in time. Explain why obvious training deficiencies were not addressed promptly and adequately at the time of their discovery by the auditors. Also, explain ARC's methodology for evaluating the adequacy of its DCSC training program.

Status: Red Cross will provide a response within 90 days of receipt of the ADL.

Order 4:
Within 45 days of receipt of this letter, provide a thorough description of ARC's system for determining the staffing levels for the mobile collection drives and submit the written procedure that describes this system.

Status: Red Cross will provide a response within 45 days of receipt of the ADL.

Order 5:
Within 60 days of receipt of this letter, provide a thorough description of the DCSC's operation for answering donor eligibility calls from collection sites, including the number of staff assigned to this function. Explain the use of inexperienced DCSC personnel answering donor eligibility

calls from collections sites. Describe what controls ARC has implemented to ensure DCSC personnel provide accurate answers to donor eligibility calls.

Status: Red Cross will provide a response within 60 days of receipt of the ADL.

Order 6:

Within 45 days of receipt of this letter, establish and implement a time frame for the Medical Director' s review of DRIRs. A timely review is critical to donor safety due to the seriousness of some donor reactions. In order to ensure that the safety of the donor is not compromised, the Medical Director's review should be completed prior to allowing a donor who has experienced a donor reaction to return for additional donations.

Status: The DCSC and Medical Directors are currently discussing appropriate ways to address this concern. This change will require submission of a Document Change Request (DCR) to ensure that a standard process for managing donor reaction evaluations is effectively implemented throughout the organization. Red Cross intends to complete document development by (b) (4)

Due to the time frame required to develop the document and effectively communicate the information to staff, Red Cross requests an extension for responding to this order and requests that the response be submitted to FDA within 120 days of receipt of the ADL.

Order 7:

Within 45 days of receipt of this letter, communicate to all collection staff personnel and management the regulatory and procedural requirements for managing and documenting donor adverse reactions. Ensure that all collection staff is adequately trained to perform this task. Report to FDA your plan to accomplish this order.

Status: Staff members were retrained on the donor adverse reactions process and procedures with the implementation of BioArch R1; all regions (except Puerto Rico) will implement BioArch R1 by (b) (4) To supplement this training, Red Cross is currently developing a workshop to present to all collections staff to address this concern. The workshop contents and expectations will be released to the field by (b) (4) Red Cross anticipates the completion of the training and documentation by (b) (4)

Due to the time frame required to effectively communicate the information to all Collections staff members, Red Cross requests an extension for responding to this order and requests that the response be submitted to FDA within 120 days of receipt of the ADL.

Order 8:

Within 60 days of receipt of this letter, develop a work around to assess whether a donor has prior names in the NDDR to ensure that unsuitable blood products are not distributed from donors who have prior names in the NDDR.

Status: A task force has been identified to assess workaround options to address the concern related to donors with prior names when the donor had a record in the NDDR. The task force is currently identifying different scenarios where this situation may occur and investigating how the Red Cross current and future software systems react when presented with these types of scenarios. Because this is a complex issue that requires a detailed analysis, Red Cross anticipates the analysis to be completed by the end of (b) (4) at which point Red Cross intends to develop an action plan based on the analysis.

Due to the time required to complete the task analysis and effectively develop an action plan, Red Cross requests an extension for responding to this order and requests that the response be submitted to FDA within 120 days of receipt of the ADL.

Order 9:

Within 60 days of receipt of this letter, perform a retrospective review of survey cards, since the time they were first issued to the date of this letter, to identify all complaints or concerns that are related to FDA regulated functions and, as required by the Decree, manage any regulated complaints/concerns as problems. Identify all regions that issue such survey cards. Additionally explain how ARC manages such complaints and concerns that are received through the internet.

Status: Red Cross is in the process of identifying all regions that issue survey cards and developing a plan to perform a retrospective review. The review requirements and expectations were released to the field via Blood Services Letter (BSL) #12-004 on February 9, 2012.

Due to the time required for the field to complete this retrospective review, Red Cross requests an extension for responding to this order and requests that the response be submitted to FDA within 120 days of receipt of the ADL.

Order 10:

Within 30 days of receipt of this letter, provide copies of all Quality Process Reviews conducted at the DCSC since the DCSC began merging of the regional donor management operations. This material was requested numerous times during the September-October 2010 Philadelphia DCSC inspection. Provide a detailed explanation why the completed Quality Process Reviews were not provided to the FDA investigators during the inspection.

Status: Red Cross' response is provided in this letter, dated February 13, 2012.

Order 11:

Within 60 days of receipt of this letter, provide a status report on ARC's 12/15/10 response to the Philadelphia DCSC FDA 483 issued on 10/29/10.

Status: Red Cross will provide a response within 60 days of receipt of the ADL.

Order 12:
Within 30 days of receipt of this letter, provide a copy and complete description of the Modified Compliance Improvement Strategy (MCIS) that the DCSC was placed on in January 2011, as well as the status of the MCIS.

Status: Red Cross' response is provided in this letter, dated February 13, 2012.

Order 13:
Within 60 days of receipt of this letter, develop and implement an SOP to require complete documentation of all information evaluated during review of any utility report including the soundex reports. Provide a copy of this SOP to FDA and include the effective date of its implementation.

Status: Red Cross is currently developing an enhancement to an existing procedure to ensure a standard process for documenting the review of any utility report including the soundex report. On January 24, 2012, BHQ approved the DCR, #14501, associated with this enhancement. Red Cross anticipates the document development and approval process to be completed by the end of February. Although an implementation date has not been set, Red Cross expects the field to fully implement the procedure no later than May 11, 2012.

Due to the time required for the field to effectively implement the updated procedure, Red Cross requests an extension for responding to this order and requests that the response be submitted to FDA within 120 days of receipt of the ADL.

Order 14:
Within 30 days of receipt of this letter, provide an explanation for the use of BPD Code QC-90-01-05 [failure to adequately manage potentially non-confirming product (product not released)] when ARC's investigation into problems determined that blood products were actually distributed. FDA noted this during the review of Exception Reports E-0780785 and E-0790730.

Status: Red Cross' response is provided in this letter, dated February 13, 2012.

Order 15:
Within 60 days of receipt of this letter, review the contents of the quarterly and annual QA reports to ensure that such reports adequately convey to ARC' s Biomedical Services senior management that serious problems or deficiencies are developing and/or have occurred. This would enable senior management to be aware of the potential risk of the developing problems/deficiencies to public health and the impact on ARC's compliance with the law and the Decree.

Status: Red Cross will provide a response within 60 days of receipt of the ADL.

Order 16:

Within 45 days of receipt of this letter, provide a list of all facilities using the hand warmers during the blood collection process. Include details regarding: when the facilities began utilizing the hand warmers, what the purpose of their use is, and why they were in use without training and a written procedure.

Status: Red Cross will provide a response within 45 days of receipt of the ADL.

Order 17:

Within 45 days of receipt of this letter, evaluate the process for performing annual competency assessments and determine the reason they consistently fail to identify employees who do not perform tasks in accordance with written procedures or manufacturer' s instructions. Report to FDA what steps you plan to take to ensure the assessments are adequate.

Status: In order to evaluate the competency assessment process, Red Cross is conducting a full task analysis of the process. This analysis will review what is being assessed, how the assessments are conducted, and the qualifications of our instructors. As part of the analysis, Red Cross will also review the current instructor training courses to determine if they appropriately prepare our instructors to effectively perform competency assessments of our employees. The task analysis will be completed by the end of (b) (4) with a full action plan based on the analysis completed by the end of (b) (4)

Due to the time required to complete the task analysis and effectively develop an action plan, Red Cross requests an extension for responding to this order and requests that the response be submitted to FDA within 90 days of receipt of the ADL.

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ATTACHMENT 3

Response to Order 2

Order 2:

Within 30 days of receipt of this letter, provide a list and a complete description of each functional team in the DCSC, including a complete list of all supplemental sites assisting with Philadelphia and Charlotte DCSC activities. Provide a status report of the staff hiring plan described in your 12/15/10 response to the Philadelphia DCSC FDA 483 issued on 10/29/10.

Response:

Background

The DCSC implemented a new functional structure in 2010 with several goals in mind:

1. To prepare for the unified database that will be introduced with the BioArch Release (b) (4) project.
2. To meet operational needs and reduce inefficient handoffs between staff.
3. To improve compliance by allowing staff and supervisors to focus on and develop process expertise in a specific function.
4. To improve employee satisfaction and reduce turnover by allowing staff to become proficient in one primary task.

Description of each DCSC Operational Functional Team

In 2010, the DCSC modified the way in which work was performed from cross-functional teams to dedicated functional teams. In order to achieve this new structure, the following functional teams were established:

- **Donor Care Specialist Team**: Responsible for managing issues related to Donor Reaction/Complication and Injury Records (DRIR/DCIR). The team has primary responsibility for significant donor complications and post donation information callbacks.
- **Donor and Client Support Specialist Team:** Responsible for retrievals including those due to repeat reactive test results and donor deferrals. The team is also responsible for reinstatements and serves as backup for the Donor Eligibility Specialist Team as needed.
- **Case Investigator Team:** Responsible for recipient complications reported by consignees. The team also has responsibility for reports of bacterial contamination and performs any gain controls/retrievals associated with these cases.
- **Donor Counselor Team:** Responsible for reviewing and signing donor notification packets associated with positive test results, donor counseling, lookback activities, donor follow-up studies, and assisting regions in releasing autologous donations with positive test results.
- **Donor Notification Specialist Team:** Responsible for confirmatory test result entry, ensuring all confirmatory results are received, preparing donor notification packets, performing state notifications, and notifying transfusion services/physicians regarding autologous donations with positive test results.

- **Donor Eligibility Specialist Team:** Responsible for addressing donor eligibility questions from Collections staff in the field as well as calls specifically from donors regarding eligibility. The team also fields questions from the general public, such as local Red Cross contact information or how to replace a lost donor card.

Any incumbent staff person was familiarized with his/her new role and affected documents related to role or process flow changes were updated. Incumbent staff moved to his/her functional role in the Philadelphia facility on June 21, 2010 and in the Charlotte facility on September 27, 2010.

New DCSC staff are assigned to or hired for functional teams based on prior experience and their ability to meet the qualification requirements for the specific functional team.

Supplemental Sites assisting with the DCSC Activities

The DCSC opens approximately 4,000 cases a month between the facilities in Philadelphia, PA and Charlotte, NC. Due to staffing challenges and workflow inefficiency experienced in 2009 and 2010, approximately 27,000 cases remained open as of November 2010; 18,000 of these cases were opened before July 1, 2010. The CIS Plan contained an approved sub-plan for the closure of the 18,000 backlog of cases pending final review and closure (process verification) by adding resources to review them. In order to clear the backlog, DCSC management enlisted the assistance of experienced staff from regions or former DCSC trained staff who could perform process verification. The DCSC Records Management department moved files physically to remote sites as needed to facilitate this review. These supplemental staff members were trained to perform the task by DCSC Training Department instructors and the training was tracked in the Red Cross Learning Management System (LMS).

The following chart lists the supplemental sites as well as the start and end date of supplemental assistance.

Supplemental Site	Staff Mix	Start Date	End Date	Comment
St. Paul, MN	(b) (4)	7/13/2010	7/22/2011	Regional staff
Dedham, MA		9/14/2010	10/7/2011	Regional staff
Florida		9/10/2010	7/2/2011	Former DCSC staff that relocated
Boise, ID		10/25/2010	9/16/2011	Regional staff
Johnstown, PA		11/15/2010	9/16/2011	Regional staff
Louisville KY		11/15/2010	6/10/2011	Regional staff

* PT = Part-time; FT = Full-time

As the number of open cases decreased, remote site support was discontinued in a staggered fashion as shown in the table above.

In addition, Red Cross signed a contract with (b) (4) , for staff augmentation in process verification. (b) staff from (b) (4) started November 15, 2010 and (b) more were added November 29, 2010. This team was located in the Charlotte DCSC

facility and performed process verifications with onsite operational, quality, and problem management support. All consultants were trained by DCSC Instructors and their training was tracked in the Red Cross LMS. The team was deactivated April 15, 2011.

Status Update of the DCSC Staff Hiring Plan

In August 2010, Red Cross determined that the donor management workload and number of staff resources required to perform the work had been underestimated. DCSC Management recognized the staff resource issue as a contributing factor to the ineffective consolidation of donor management activities. The following actions were taken:

1. A staffing plan was established to add additional operational positions as part of the CIS. The staffing plan accommodated current workload challenges, expected vacancies from turnover and length of time to train new staff. The Operational Staffing Plan was initiated in July 2010 and DCSC reached a "staffing to plan" status in December 2010 even though newly hired staff members were not yet released to task.
    a. The plan identified (b) (4) additional Donor Eligibility Specialists to accommodate calls from donors and regional sites.
    b. The plan identified (b) (4) Case Review Specialists (a new function) to perform Process Verification of cases.
    c. The plan identified (b) (4) additional Donor and Client Support Specialists (DCSS) to accommodate retrieval workload and open case file management. Additional positions were added to this retrieval group after the staffing plan was established.
    d. The plan identified (b) (4) additional Donor Care Specialists to accommodate faster response time to donor complications.
    e. An additional (b) (4) Donor Notification Specialist and Counselor staff were hired to accommodate test result management and lookback cases.
    f. An additional (b) (4) positions were hired in the other functional groups.

    Approximately (b) (4) staff members were hired in this timeframe as shown in the table below.

FTE Summary Operations	July 31, 2010	Dec. 31, 2010	July 31, 2011	Dec. 31, 2011
Budget	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Actual	(b) (4)	(b) (4)	(b) (4)	(b) (4)

2. Annualized Turnover decreased from 29.9% for first quarter FY2010 to 17.8% by fourth quarter FY2011 reflecting improved workload, supervision, and management. A new hire calculator was developed as part of the CIS plan to ensure DCSC is maintaining staffing levels within approximately 5% of established targets.

Description of DCSC Quality Assurance and Problem Management Teams

The DCSC maintains Quality Assurance (QA) and Problem Management (PM) departments at both facilities (Philadelphia, PA and Charlotte, NC) in accordance with the Red Cross Quality System policies and requirements. The quality organization is integrated into the DCSC with a separate reporting structure from operations through the Senior Quality Director to the quality executive management of the company. The functional responsibility of each group is described below.

Quality Assurance

The QA staff members provide independent review and approval of policies, procedures, protocols and work instructions through review, analysis, and observation. In addition, QA staff members perform approval and release functions for such areas as corrective and preventive action, record review in all areas of the Quality Management System, complaint handling, identification and traceability activities, validations, statistical techniques, handling, and process activities in donor management, product retrieval, and donor complications.

Problem Management

The DCSC is dedicated to preventing problems, continuously improving the processes, and correcting procedures in order to ensure achievement of Red Cross strategic goals of providing the highest quality blood products and services. PM staff members are involved in monitoring, measurement, analysis and improvement activities needed to:

- Ensure conformity of the Quality Management System
- Continually improve the effectiveness of the Quality Management System

PM staff members, in accordance with System 10, *Problem Management*, procedures, facilitate actions to eliminate the cause of nonconformities in order to prevent recurrence. Staff members assist with corrective action development/planning as appropriate. Problems are managed according to procedures and may be filed or initiated by any employee that identifies the situation; however, management of problem investigations and resolution is performed by trained employees using the Red Cross (b) (4) [redacted].

Status Update of the QA/PM Staff Hiring Plan

The Red Cross underestimated the donor management workload and number of staff resources required to manage the associated QA and PM workload. The Red Cross Quality Management team recognized staffing levels as a contributing factor to the ineffective consolidation of donor management activities. The following actions were taken:

1. A staffing plan was established prior to the 2010 Philadelphia DCSC FDA inspection to add additional QA and PM in 2010. The staffing plan was associated with the estimated final work load based upon information obtained from evaluating the backlog of operational cases.
    a. (b) (4) additional QA positions - October through December 2010
        - (b) (4) QA Officer/Inspection Coordinator- October 2010
        - [redacted] QA Specialists (b) (4) [redacted] - October 2010, December 2010

b. [redacted] additional PM positions - January 2010 [redacted]

2. PM staffing evaluation in 2011 approved [redacted] additional PM positions to begin January 2012 [redacted]
3. Current QA/PM staffing includes a total of [redacted] Full Time Equivalent (FTE) positions as of January 2012: Note – this is an increase of [redacted] total FTEs ([redacted] PM, [redacted] QA) from the June 2009 original staffing model.
   a. [redacted] PM staff – [redacted] line staff, [redacted] managers, [redacted] director
   b. [redacted] QA staff – [redacted] line staff, [redacted] managers, [redacted] senior director
   c. PM – [redacted] FTEs dedicated support from South Central Division
   d. [redacted] shared administrative position
4. Additional resources from other Red Cross facilities were allocated on a temporary basis to assist with the impact of the workload challenges for both the QA/PM functions. The FTEs denoted below are based upon equivalent hours as different individual staff may have assisted through out the time denoted.
   a. In 2010
      - PM - [redacted] FTEs from the Western Division, [redacted] FTEs from the Mid-American Division.
      - QA - [redacted] FTEs from various Red Cross divisions for Quality System Review and [redacted] problem review and approval.
   b. In 2011
      - PM – [redacted] FTEs from the South Central Division, [redacted] FTE from the Western Division, [redacted] FTE from the Southern Division, [redacted] FTE from multiple other divisions. This work was concentrated in the January through March 2011 timeframe.
      - QA - [redacted] FTE from various Red Cross divisions for problem review and approval.
5. Change in senior QA/PM leadership at the DCSC occurred in 2010/2011. Both the new Senior Quality Director (hired April 2011) and the Director of Problem Management (hired July 2011) each have more than 20 years of Red Cross experience.
6. Additional temporary resources were hired to assist with the impact of the workload challenges for both the QA/PM functions. Although acquired through an external temporary agency, approximately half of the staff had current/recent Red Cross experience. In 2011, these temporary resources equated to [redacted] FTEs (greater than [redacted] hours from December 2010-December 2011).
7. Turnover in the QA and PM departments for 2011 was minimal
   a. QA - no staff turnover.
   b. PM - [redacted] staff turnover.

In summary, DCSC QA/PM staffing has increased throughout the life of the DCSC and temporary designated help was provided in 2010-2011 to assist with the backlog of problems and increased workload associated with the closure of the backlog cases in DCSC operations. The staffing plan in June 2009 consisted of [redacted] QA/PM staff; the current staffing plan includes [redacted] QA/PM staff.

Response to Order 10

Order 10:

Within 30 days of receipt of this letter, provide copies of all Quality Process Reviews conducted at the DCSC since the DCSC began merging of the regional donor management operations. This material was requested numerous times during the September-October 2010 Philadelphia DCSC inspection. Provide a detailed explanation why the completed Quality Process Reviews were not provided to the FDA investigators during the inspection.

Response:

Subsequent to the 2010 Philadelphia DCSC FDA inspection, Red Cross confirmed that Quality Process Reviews had been conducted at the DCSC in 2008, 2009, and 2010. Red Cross apologizes for failing to provide these to the investigators at the time of the inspection. Upon the initial request by the investigators, QA staff at the facility incorrectly indicated that no reviews had been performed since there were no Philadelphia facility-specific reviews performed in 2010. Documentation of completed reviews is maintained at the Charlotte facility. Although staff requested and received copies of all the reviews conducted from 2008 and 2009, the documents were not provided to the investigator as staff believed that the investigators were requesting only the 2010 Quality Process Reviews, which had not been completed at the time of the inspection.

The following system reviews were conducted and are included as Exhibit 1.

System	CY 2008 Month(s) Completed	CY 2009 Month(s) Completed	CY 2010 Month(s) Completed	CY 2011 Month(s) Completed
1) Management				
2) Quality Assurance				
3) Policy and Procedure Management				
4) Training and Personnel Competency				
5) Facilities Management				
6) Validation[1]				
7) Information and Data Management				
8) Equipment Management				
9) Change Control				
10) Management Customer Concerns				
11) Suspect Product Review				
12) Supplier Quality				
13) Material Management				

(b) (4)

System	CY 2008 Month(s) Completed	CY 2009 Month(s) Completed	CY 2010 Month(s) Completed	CY 2011 Month(s) Completed
14) Donation Recruitment and Qualification Management		(b) (4)		
15) Collection/Procurement				
16) Clinical/Transfusion Services				
17) Product Manufacturing/Processing				
18) Laboratory Testing				
19) Finished Product Quality Control				
20) Quarantine/Lot Release/Labeling[2]				
21) Storage, Shipping and Return				
22) Information Technology				

NOTES:

- DCSC operations started in May 2008.
- NA – systems not applicable to the DCSC.
- Shaded areas indicate no review was conducted or no record of the review could be located.
- Unless otherwise noted, the review month(s) provided in the table indicates a review of both the Charlotte, NC and Philadelphia, PA facilities was completed.

[1] DCSC does not have any regulated equipment that falls under the System 6 guidelines. The computer validation/qualification tasks reviewed in conjunction with System 6 in 2009 are now evaluated as part of System 22

[2] The receipt/entry/modification of test result tasks reviewed in conjunction with System 20 in 2009 are now evaluated as part of Systems 11 and 14.

Response to Order 12

Order 12:

Within 30 days of receipt of this letter, provide a copy and complete description of the Modified Compliance Improvement Strategy (MCIS) that the DCSC was placed on in January 2011, as well as the status of the MCIS.

Response:

Background

The Red Cross Biomedical Services Headquarters (BHQ) Quality and Compliance Oversight Committee (QCOC) exists under the authority of the President, Biomedical Services, to provide an increased level of oversight and influence over all cGMP regulated activities. The primary purpose for this increased oversight is to ensure that Red Cross BHQ is consistently focusing appropriate efforts on the improvement of its quality and compliance profile and does not allow other priorities to adversely impact it.

The BHQ QCOC provides oversight of quality and compliance by reviewing the analysis of multiple sources of data to ascertain that all operational facilities (regions, labs, divisions, DCSC, BHQ support functions, etc.) are focusing appropriate efforts to maintain and, where necessary, to improve quality performance and compliance.

On July 7, 2010, BHQ QCOC notified DCSC management of its decision to place the DCSC under a Compliance Improve Strategy (CIS) plan. The reasons for the decision are described in Exhibit 2.

In January 2011, the QCOC recognized that the DCSC had made some improvements in its operations based on the CIS plan; however, additional improvements were required to address the seriousness of the DCSC issues. Therefore, on January 14, 2011, the QCOC placed the DCSC on a Modified Compliance Improvement Strategy (MCIS). The reasons for this decision are described in Exhibit 3.

Description of MCIS

The MCIS plan consisted of the following key elements:

- Assessing management and line staff for job performance, disciplinary actions and problem rate to identify any skill gaps.
- Identifying corrective actions to address management and staff needs.
- Delivering workshops for core and functional teams to provide them with a deeper knowledge of the compliance purpose and critical areas of compliance.
- Assessing the DCSC compliance culture through staff interviews following the completion of these activities.

(b) (4) [redacted]

(b) (4)

[redacted]

MCIS Project Plan

The DCSC developed a project plan to monitor and track all activities to ensure that all aspects of the MCIS were accomplished. The MCIS project management plan is provided as Exhibit 4. The major deliverables are listed below.

- Plan for conducting Management and staff assessment and associated tools.
- Summary of management assessment outcomes including individual and/or DCSC-wide corrective actions.
- Materials for core refresher and functional workshops.
- Post-MCIS compliance culture interview tool for staff.

Status of the MCIS

Staff Assessment

On April 21, 2011, Red Cross completed the assessment of DCSC management staff. A Red Cross executive interviewed staff using a standard questionnaire which identified three areas of development for all supervisors. The following workshops were then developed.

- "Problem Management for Supervisors" was delivered June 2011.
- "Coaching Staff" was delivered in December 2011.
- "Managing Delegation" was delivered in December 2011.

On October 7, 2011, the DCSC completed the assessment of line staff. Line staff members were evaluated using the problem rates, individual work performance reviews, and staff interview results.

In addition, a Management Action Form (MAF) was created to address unique needs for both management and line staff with additional skill gaps.

Workshops

All DCSC staff attended six core workshops over a two-day period.

- Patient and Donor Safety
- Blood Fundamentals
- Techniques for a Good Review
- Management of Suspect Products
- Problem Management
- Customer Service

Staff also attended functional workshops based on the tasks that they were assigned to perform. Supervisors attended all workshops for their functional area, as well as those for broader topics, such as Advanced Customer Service. The functional workshops are listed below.

- Advanced Customer Service
- Advanced Case File Management
- Adverse Donor Reactions
- Lookback Case Management
- Retrievals Management
- Proper Completion of a Donor Status Change Record (DSCR) and Component Status Change Record (CSCR)
- Requesting the Correct Letters

Following the workshops, a Red Cross senior manager interviewed line staff using a standard questionnaire. The DCSC established the compliance culture score on a scale of 1.0 through 5.0 with b4 being defined as Meets Expectations; the overall results of the staff interviews indicated a score of 3.55.

Summary

Each month, the DCSC reports to the QCOC on the status of the MCIS and CIS and the improvements it has achieved. Completed milestones are listed below:

- The DCSC has completed all actions for the MCIS.
- Management and line staff assessments and management action form tasks are complete.
- DCSC management initiated a series of b4 staff communications in November 2011. The goals of these communications are to remind staff of the topics covered in the six core workshops to sustain a vigilant focus on quality and compliance.
- DCSC MCIS project leadership and BHQ Quality Support review established metrics b4 to track progress of the MCIS activities. Regular monitoring for the MCIS was discontinued in December 2011 when all MCIS tasks were completed. Metrics that DCSC management monitored included:
    - Critical tasks and risks
    - Staff and management attendance at workshops
    - Customer concerns
    - Call abandon-rate and queue time
    - Open case load
- DCSC Management reports on the MCIS progress, as well as, the CIS progress at least b4 to the QCOC.
- DCSC and BHQ management staff use the DCSC Dashboard (Exhibit 5) to monitor current performance and progress.
- BHQ QCOC, with collaboration from the DCSC, developed effectiveness check measures (Exhibit 6) which was approved at the February 9, 2012 QCOC meeting.

In summary, the DCSC has made measurable progress, but there is more to do. The BHQ QCOC will monitor DCSC performance for at least b4 post corrective action completion to ensure that the improvements seen to date are sustainable.

Response to Order 14

Order 14:

Within 30 days of receipt of the letter, provide an explanation for the use of BPD Code QC-90-01-05 [failure to adequately manage potentially non-conforming product (product not released)] when ARC's investigation into problems determined that blood products were actually distributed. FDA noted this during the review of Exception Reports E-0780785 and E-0790730.

Response:

Biological Product Deviation (BPD) Code QC-90-01-05 is used to track problems in which potentially non-conforming products were not appropriately controlled to prevent further distribution, but in which those potentially non-conforming products were not distributed after the problem was identified.

Red Cross' investigation into the use of BPD Code QC-90-01-05 in the two cited exceptions determined that this was the most appropriate BPD Code available at the time the problems were discovered. In both cases, all distributed components had been shipped prior to the date the disqualifying information was received by Red Cross. Had the components been shipped after disqualifying information was received, the most appropriate BPD Code would have been associated with BPD Code category QC-94, *Distribution of product that did not meet specifications*. The facts surrounding each of these problems are detailed below.

Exception Report E-0780785 addresses a donor who was deferred at a blood drive on March 7, 2010 for taking Proscar. The DCSC followed up with the donor on March 19, 2010 and determined that the start date for taking the medication was January 1, 2009. At the time this disqualifying information was received, eight affected components from four donations had already been shipped to consignees. There was one in-date distributed component associated with Whole Blood Number (WBN) (b) (6) (Product Code 18435 – Plasma Cryoprecipitate Reduced). DCSC staff failed to promptly place an electronic hold on the affected component and failed to notify the consignees as required within 48 hours of receipt of the disqualifying information. Since no components were distributed subsequent to the receipt of the disqualifying information, the failure mode was determined to be "48 hour consignee notification not performed."

Exception Report E-0790730 addresses a donor who called the DCSC to report a positive HCV test on April 12, 2010. Although an assertion was added to the donor's record on the same day, the appropriate electronic holds were not placed on the two affected in-date components, both of which had been distributed prior to receipt of the disqualifying information. DCSC staff followed component retrieval guidelines and identified two affected components associated with one donation, WBN (b) (6). DCSC staff notified the consignee for one component (Product Code 04710 – AS-1 Red Blood Cells Leukoreduced (Filt)) within 48 hours; however, staff failed to notify the consignee for the other component (Product Code 19701 – Recovered Plasma <24 Hrs MFG) until four days later. Since no components were distributed subsequent to the receipt of the disqualifying information, the failure mode was determined to be "48 hour consignee notification not performed."

At the time these problems were identified in early 2010, the following two BPD Codes were available to track problems with retrieval/gain control activities:

- BPD Code: MI-00-01-19, *Recall/Market Withdrawal not performed/complete/ timely*, Risk Indicator = (b) (4)
- BPD Code: MI-00-01-23, *Recall/Market Withdrawal records incorrect/ incomplete,* Risk Indicator = (b) (4)

Red Cross recognized that in each of the cited problems, failure to notify the consignee could have resulted in inadequate management of a non-conforming component at the consignee locations. To support appropriate tracking and trending of these failures, QC-90-01-05 with a Risk Indicator = (b) (4) (highest risk level), was deemed most appropriate to ensure adequate investigation of the problem.

Red Cross determined that additional BPD Codes were needed to distinguish between different types of failures to completely execute all required component notification and retrieval actions. Three new BPD Codes and two modified BPD Codes in the Red Cross Category MI-OF: *Problems with retrieval, recall, and market withdrawals*, were submitted to FDA as part of requested revisions to Job Aid 10.4.ja002, *Biological Product Deviation Codes*. These codes were approved by FDA on April 26, 2010, and implemented by September 1, 2010. Since that date, one of these new BPD Codes, MI-00-01-39, *Retrieval/Gain Control Activity: 48 hour notification to consignee not performed/complete/ timely for distributed in-date products,* Risk Indicator = (b) (4) has been used to code problems of a nature similar to those described above.