DEPARTMENT	OF HEALTH AND HU	MAN SERVICES
FOOD AND DRUG ADMINISTRATION		

DISTRICTORFOCE ADDRESS AND PROONE NUMBER  1 Montvale Avenue  Stonebam, MA 02180  713-15-95-7700  NAME AND THIS OF HOMONOLA TO WHOM REPORTS ISSUED  TO: Paul T. Sullivan, CEO  FRAM NAME  American Red Cross Blood Services  1273014  STREET ADDRESS  American Red Cross Blood Services  1774 OF EVALUATION OF THE PROPERTY OF THE FAN REPRESENTATIVES DURING THE REPRESENTATIVES DURING THE REPRESENTATIVE OF THE FAN REPRESENTATIVE OF THE F				
Stoneham, MA 02180   FRINMER   1273014   12730		The state of the s		
NAME AND THIS OF HONORULA TO WHOM REPORTS ISSUED  TO: Paul T. Sullivan, CEO FREM NAME  AMERICAN Red Cross Blood Services  GIV. STATE AND IP COOR  FRAM NAME  AMERICAN Red Cross Blood Services  GIV. STATE AND IP COOR  FARMINGTON, CT 06032  THE FOA REPRESENTATINGS DURING THE MISSECTION OF YOUR FAGURY. THEY ARE INSPECTIONAL OSSERVATION, OR NO DO NOT REPRESENT A THILL AGENCY DETERMINATION RECARDING YOUR COMPULANCE, IF YOU HAVE AN OBJECTION REGARDING AND OSSERVATIONS, AND DO NOT REPRESENT A THILL AGENCY DETERMINATION RECARDING YOUR COMPULANCE, IF YOU HAVE AN OBJECTION REGARDING AND SERVATION, OR HAVE BRIDE HERE OF PLAN TO MELMENT CORRESPONDE AND OSSERVATION, OR HOUSE BRIDE OF PLAN THE PHONE NUMBER AND ADDRESS ABOVE.  DURING AN INSPECTION OF YOUR FREM () (ME) GESERVED:  Observation 1  Pailure to adequately investigate, correct, and prevent recurring problem of distributing blood and blood components without ice to consignee. This was a BIRCH investigation. The consignee was instructed to destroy the units by Hospital Services Supervisor referred (30). No hold was placed on the units. A corrective action, and a three months effectiveness check from June to August were developed and implemented. On 9/9/08 during OA review of present of the problem involved distribution of 23 red blood cell without ice to consignee. This issue also resulted in consignee was opened on 7/17/08. The problem involved distribution of 23 red blood cell without ice to consignee. This issue also resulted in consignee being instructed to destroy the units by 10 No hold was placed on the units. A corrective action was developed and implemented; and a months effectiveness checks from September to November was implemented; and a months effectiveness checks from September to November was implemented; and a months effectiveness checks from September to November was implemented; and a months effectiveness checks from September to November was implemented; and a months effectiveness checks from September to November was implemented.  Observation 2  Writ				
INME AND TITLE OF NOWIDUAL TO WHOM REPORTS ISSUED  TO: Paul T. Sullivan, CEO  FREM NAME  American Red Cross Blood Services  OTY, STAR PAID DF COOD  TYPE OF ESTABLISHMENT INSPECTED  Licensed Blood Betablishment  THIS DOCUMENT USTS OSSERVATIONS MADE BY THE FDA REPRESENTATIVES DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OSSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENTED, OR PLAN TO IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OSSERVATION, YOU MAY DECISIONS, PLANE CONTACT FOR AT THE PHONE NAMEER AND ADDRESS ABOVE.  DURING AN INSECTION OF YOUR FREM () (WE) OSSERVED:  Observation 1  Failure to adequately investigate, correct, and prevent recurring problem of distributing blood and blood components without ice to consignees.  Specifically,  a. The problem for DIAL Was discovered on 3/20/08. The problem involved shipment of 16 red blood cells without ice to a consignee. This was a DIAL investigation. The consignee was instructed to destroy the units by Hospital Services Supervisor referred (JO). No hold was placed on the units. A corrective action, and a three months effectiveness check from June to August were developed and implemented. On 9/9/08 during QA review of DIAL TO A CONTROL OF THE PROBLEM OF THE				
TO: Paul T. Sullivan, CEO FREM NAME Namerican Red Cross Blood Services  GIV. STATE RAND DP COOE  FARTMINGTON, CT 06032  THE GOOLMENT USTS OSSERVATIONS MADE BY THE FDA REPRESENTATIVES DURING THE ROSPECTION OF YOUR FACULTY. THEY ARE INSPECTIONAL OSSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION RECARDING YOUR COMPULANCE, IF YOU HAVE AN OSSERVATION, ON SERVATION, ON READ REPRESENTATIVES DURING THE ROSPECTION OR ACTION WITH HE FDA REPRESENTATIVES DURING THE ROSPECTION OR OSSERVATION OR ON SERVENTION OR SHEET OF HAVE IN THE PHONE NUMBER AND ADDRESS ABOVE.  DURING AN INSPECTION OF YOUR FREM () (ME) OSSERVED:  Observation 1  Failure to adequately investigate, correct, and prevent recurring problem of distributing blood and blood components without ice to consignees.  Specifically,  a. The problem for 1014  was discovered on 3/20/08. The problem involved shipment of 16 red blood cells without ice to a consignee. This was a 1014  investigation. The consignee was instructed to destroy the units by Hospital Services Supervisor referred (30). No hold was placed on the units. A corrective action, and a three months effectiveness check from June to August were developed and implemented. On 9/9/08 during OA review of 1014  b. On 7/16/08 another incident regarding shipment of red cell without ice to consignee cocurred; an exception (1014)  b. On 7/16/08 another incident regarding shipment of red cell without ice to consignee being instructed to destroy the units by 100 No hold was placed on hold.  b. On 7/16/08 another incident regarding shipment of red cell without ice to consignee being instructed to destroy the units by 100 No hold was placed on the units. A corrective action was opened on 7/17/08. The problem involved distribution of 23 red blood cell without ice to consignee. This issue also resulted in consignee being instructed to destroy units, instead of referring the customer complaints to ARC, Deckman of the procedure was not followed regarding handling of "Management of Suspect Products".  Specificall		1273014		
American Red Cross Blood Services  209 Farmington Avenue  TYPEOF ESTABLISHMENT INSPECTED  Licensed Blood Establishment  Licensed Blood Establishment  Licensed Blood Establishment  Licensed Blood Establishment  DOUBLENT LIST OSSERVATIONS MADE BY THE FOA REPRESENTATIVES) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL  OSSERVATION, OR HAVE IMPLEMENTED, OR FAIN A RESIDENTIAN OF YOUR FACILITY. THEY ARE INSPECTIONAL  OSSERVATION, OR HAVE IMPLEMENTED, OR FAIN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OSSERVATION, ON MAD VIBEOUSS THE  OSSERVATION, OR HAVE HERE ESTABLISHMENT HERE INSPECTION OR SUBMIT THIS INFORMATION TO FOA AT THE ADDRESS ABOVE. IF  OURING AN INSPECTION OF YOUR FIRM (0) (NE) OSSERVED:  Observation 1  Failure to adequately investigate, correct, and prevent recurring problem of distributing blood and blood components without ice to consignees.  Specifically,  a. The problem for (1) (1) was discovered on 3/20/08. The problem involved shipment of 16 red blood cells without ice to a consignee. This was a (1) investigation. The consignee was instructed to destroy the units by Hospital Services Supervisor referred (JO). No hold was placed on the units. A corrective action, and a three months effectiveness check from June to August were developed and implemented. On 9/9/08 during QA review of (1) (1) resulted in problem (1) to address why units were not placed on hold.  b. On 7/16/08 another incident regarding shipment of red cell without ice to consignee occurred; an exception (1) (2) was opened on 7/17/08. The problem involved distribution of 23 red blood cell without ice to consignee. This issue also resulted in consignee being instructed to destroy the units by (1) No hold was placed on the units. A corrective action was developed and implemented; and (1) Hospital Services Supervisor (JO) instructed the consignees to destroy units, instead of referring the customer complaints to ARC, peddam, MA for follow up, as it's written in ARCHS (IV)  EMPLOYEED MAME AND THE FORMER TOWN.  EMPLOYEED				
American Red Cross Blood Services  GIY, STATE AND JP CODE  Farmington, CT 06032  Licensed Blood Establishment  This DOCUMENT USTS GREENVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURNG THE INSPECTION OF YOUR FACULTY. THEY ARE INSPECTION. OSSERVATIONS, AND DA NOT REPRESENT A THAN LABOUR DETERMANTION REMARKS OF CONFIDENCE IF YOU MANK AN GREETON ARE AND ADDRESS AS INCOME.  SUBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURNG THE INSPECTION OR YOUR FACULTY. THEY ARE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.  DURING AN INSPECTION OF YOUR FIRM () (NE) OSSERVED:  Observation 1  Failure to adequately investigate, correct, and prevent recurring problem of distributing blood and blood components without ice to consignees.  Specifically,  a. The problem for (1) was discovered on 3/20/08. The problem involved shipment of 16 red blood cells without ice to a consignee. This was a (1) investigation. The consignee was instructed to destroy the units by Hospital Services Supervisor referred (10). No hold was placed on the units. A corrective action, and a three months effectiveness check from June to August were developed and implemented. On 9/9/08 during QA review of (1) on the consignee occurred; an exception (1) on the consignee was opened on 7/17/08. The problem involved distribution of 23 red blood cell without ice to consignee. This issue also resulted in onsignee being instructed to destroy the units by (1) No hold was placed on the units. A corrective action was developed and implemented; and (2) No hold was placed on the units. A corrective action was developed and implemented; and (3) Monthly (1) No hold was placed on the units. A corrective action was developed and implemented; and (3) Monthly (1) No hold was placed on the units. A corrective action was developed and implemented; and (3) Monthly (1) No hold was placed on the units. A corrective action was developed and implemented.  Observation 2  Written		Company to the same of the sam		
CITY, STATE AND ZP CODE  Farmington, CT 06032  THE FOA REPRESENTATIVES DUMBNITH USTS GOSSERVATIONS MADE BY THE FOA REPRESENTATIVES DUMBNITH USTS GOSSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION RECARDING YOUR COMPLIANCE, IF YOU HAVE AN GRIECTION REGARDING NOR OF NOW REPORT AND ADDRESS THE GOSSERVATION, AND DO NOT REPRESENTATIVES DUMBNITH THE HEAR PREPRESENTATIVES DUMBNISH THE INSPECTION OR ACTION WITH THE FOA REPRESENTATIVES DUBRNISH THE INSPECTION OR SUBMIT THIS INFORMATION TO FOA AT THE ADDRESS ABOVE. IF YOU HAVE AN OBJECTION REPRESENTATIVES DUBRNISH THE INSPECTION OR SUBMIT THIS INFORMATION TO FOA AT THE ADDRESS ABOVE. IF YOU HAVE AN OBJECTION OR ACTION WITH THE FOA REPRESENTATIVES DUBRNISH THE INSPECTION OR SUBMIT THIS INFORMATION TO FOA AT THE ADDRESS ABOVE. IF YOU HAVE AN OBJECTION AT THE HONE NUMBER AND ADDRESS ABOVE.  DURING AN INSPECTION OF YOUR FIRM (1) (WE) OBSERVED:  Observation 1  Failure to adequately investigate, correct, and prevent recurring problem of distributing blood and blood components without ice to consignees.  Specifically,  a. The problem for DO Was adiscovered on 3/20/08. The problem involved shipment of 16 red blood cells without ice to a consignee. This was a DO Investigation. The consignee was instructed to destroy the units by Hospital Services Supervisor referred (30). No hold was placed on the units. A corrective action, and a three months effectiveness check from June to August were developed and implemented. On 9/9/08 during QA review of DO INCOMPANY OF THE TOWN OF	FIRM NAME	STREET ADDRESS		
Farmington, CT 06032  THIS DOCUMENT USIS OSSERVATIONS MADE BY THE FDA REPRESENTATIVES) DURING THE MEPETION OF YOUR FAMALINT. THEY ARE INSPECTIONAL DISCOVERY WITH SET OF THE PAME ASSERVATION, OR HAVE MADE HAVE AND ONOT REPRESENT A FINAL ACENCY DETERMINATION RECARDING THE OWNER OF YOUR FAMALING DURING THE RESPECTION OR USE OWNER. IN ORDER ON A DISCOVERY OF THE ATT OF MADE HAVE AND OBSERVATION, YOU MAD NOT REPRESENT A FINAL ACENCY DETERMINATION FOR HAVE MADE HAVE AND OBSERVATION, YOU MAD NOT REPRESENT OF THE ATT THE PROPER HAVE AND OBSERVATION, YOU MAD NOT HE ADDRESS ASSOVE.  DURING AN INSPECTIONO OF YOUR FIRM () (NE) OSSERVED:  Observation 1  Failure to adequately investigate, correct, and prevent recurring problem of distributing blood and blood components without ice to consignees.  Specifically,  a. The problem for () (A) was discovered on 3/20/08. The problem involved shipment of 16 red blood cells without ice to a consignee. This was a (DITU) investigation. The consignee was instructed to destroy the units by Hospital Services Supervisor referred (JO). No hold was placed on the units. A corrective action, and a three months effectiveness check from June to August were developed and implemented. On 9/9/08 during OA review of (JO) (A) to address why units were not placed on hold.  b. On 7/16/08 another incident regarding shipment of red cell without ice to consignee occurred; an exception (DITO) was opened on 7/17/08. The problem involved distribution of 23 red blood cell without ice to consignee. This issue also resulted in consignee being instructed to destroy the units by (DITO) (D	American Red Cross Blood Services	209 Farmington Avenue		
THIS DOCUMENT USTS OSSERVATIONS MADE BY THE FOR REPRESENTATIVES) DURING THE INSPECTION OF VOIR FACULTY. THEY ARE INSPECTIONAL CORSERVATION, AND DO NOT REPRESENT A TIME ACRIVE YEAR AND ADDRESS AS AND DO NOT REPRESENTATION OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OSSERVATION, YOU MAY DISCUSS THE OSSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OSSERVATION, YOU MAY DISCUSS THE OSSERVATION, OR HAVE MAY QUESTIONS, PLEASE CONTACT FOA AT THE PHONE NUMBER AND ADDRESS ABOVE.  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  SPECIFICALLY,  a. The problem for THE ADDRESS ABOVE.  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  SPECIFICALLY,  a. The problem of DIA (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION O	CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED		
THIS DOCUMENT USTS OSSERVATIONS MADE BY THE FOR REPRESENTATIVES) DURING THE INSPECTION OF VOIR FACULTY. THEY ARE INSPECTIONAL CORSERVATION, AND DO NOT REPRESENT A TIME ACRIVE YEAR AND ADDRESS AS AND DO NOT REPRESENTATION OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OSSERVATION, YOU MAY DISCUSS THE OSSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OSSERVATION, YOU MAY DISCUSS THE OSSERVATION, OR HAVE MAY QUESTIONS, PLEASE CONTACT FOA AT THE PHONE NUMBER AND ADDRESS ABOVE.  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  SPECIFICALLY,  a. The problem for THE ADDRESS ABOVE.  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  SPECIFICALLY,  a. The problem of DIA (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AN INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION OF YOUR FIRM (1) (ME) OSSERVED:  DURING AND INSPECTION O	Farmington, CT 06032	Licensed Blood Establishment		
Observation 1  Failure to adequately investigate, correct, and prevent recurring problem of distributing blood and blood components without ice to consignees.  Specifically,  a. The problem for the problem for the problem involved shipment of 16 red blood cells without ice to a consignee. This was a three problem involved shipment of 16 red blood cells without ice to a consignee. This was a shift investigation. The consignee was instructed to destroy the units by Hospital Services Supervisor referred (JO). No hold was placed on the units. A corrective action, and a three months effectiveness check from June to August were developed and implemented. On 9/9/08 during QA review of the consignee occurred; an exception (10) was opened on 7/17/08. The problem involved distribution of 23 red blood cell without ice to consignee. This issue also resulted in consignee being instructed to destroy the units by (10) No hold was placed on the units. A corrective action was developed and implemented; and a 3 months effectiveness checks from September to November was implemented.  Observation 2  Written procedure was not followed regarding handling of "Management of Suspect Products".  Specifically,  On 3/20/08 and 7/17/08 (10) and (10) Hospital Services Supervisor (JO) instructed the consignees to destroy units, instead of referring the customer complaints to ARC, Dedham, MA for follow up, as it's written in ARCBS (10) (10) apply the appropriate hold of assertion was not following procedure.  EMPLOYEE(S) SIGNATURE (11) ANCE (	THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF			
Failure to adequately investigate, correct, and prevent recurring problem of distributing blood and blood components without ice to consignees.  Specifically,  a. The problem for [10] was discovered on 3/20/08. The problem involved shipment of 16 red blood cells without ice to a consignee. This was a [10] investigation. The consignee was instructed to destroy the units by Hospital Services Supervisor referred(JO). No hold was placed on the units. A corrective action, and a three months effectiveness check from June to August were developed and implemented. On 9/9/08 during QA review of [10] resulted in problem [10] to address why units were not placed on hold.  b. On 7/16/08 another incident regarding shipment of red cell without ice to consignee occurred; an exception [10] was opened on 7/17/08. The problem involved distribution of 23 red blood cell without ice to consignee. This issue also resulted in consignee being instructed to destroy the units by [10] No hold was placed on the units. A corrective action was developed and implemented; and a 3 months effectiveness checks from September to November was implemented.  Observation 2  Written procedure was not followed regarding handling of "Management of Suspect Products".  Specifically,  On 3/20/08 and 7/17/08 [10] and [10] Hospital Services Supervisor (JO) instructed the consignees to destroy units, instead of referring the customer complaints to ARC, Dedham, MA for follow up, as it's written in ARCBS [10] and [10] apply the appropriate Bold of assertion [10] apply [1	DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:			
Specifically,  a. The problem for (a) (b) (c) (c) (c) (c) (c) (d) (c) (d) (e) (e) (e) (e) (e) (e) (e) (e) (e) (e	Observation 1			
a. The problem for was discovered on 3/20/08. The problem involved shipment of 16 red blood cells without ice to a consignee. This was a placed investigation. The consignee was instructed to destroy the units by Hospital Services Supervisor referred (JO). No hold was placed on the units. A corrective action, and a three months effectiveness check from June to August were developed and implemented. On 9/9/08 during QA review of resulted in problem to address why units were not placed on hold.  b. On 7/16/08 another incident regarding shipment of red cell without ice to consignee occurred; an exception (D/4) was opened on 7/17/08. The problem involved distribution of 23 red blood cell without ice to consignee. This issue also resulted in consignee being instructed to destroy the units by No hold was placed on the units. A corrective action was developed and implemented; and a months effectiveness checks from September to November was implemented.  Observation 2  Written procedure was not followed regarding handling of "Management of Suspect Products".  Specifically,  On 3/20/08 and 7/17/08 (D/4) and (D/4) Hospital Services Supervisor (JO) instructed the consignees to destroy units, instead of referring the customer complaints to ARC, Dedham, MA for follow up, as it's written in ARCBS (D/4) apply the appropriate hold of asserted the consignees.  EMPLOYEE(S) NAME AND TILE (Print or Type) ATTE (SUED AND TILE (Print or Type) ATTE (SUED AND TILE (Print or Type) ATTE (Print or Type) ATTE (SUED AND TILE (Print or Type) ATTE (				
red blood cells without ice to a consignee. This was a local investigation. The consignee was instructed to destroy the units by Hospital Services Supervisor referred (JO). No hold was placed on the units. A corrective action, and a three months effectiveness check from June to August were developed and implemented. On 9/9/08 during QA review of resulted in problem local to address why units were not placed on hold.  b. On 7/16/08 another incident regarding shipment of red cell without ice to consignee occurred; an exception (1974) was opened on 7/17/08. The problem involved distribution of 23 red blood cell without ice to consignee. This issue also resulted in consignee being instructed to destroy the units by No hold was placed on the units. A corrective action was developed and implemented; and a 3 months effectiveness checks from September to November was implemented.  Observation 2  Written procedure was not followed regarding handling of "Management of Suspect Products".  Specifically,  On 3/20/08 and 7/17/08 (1974) and (1974) Hospital Services Supervisor (JO) instructed the consignees to destroy units, instead of referring the customer complaints to ARC, Dedham, MA for follow up, as it's written in ARCBS (1974) Another three streets of the consignees of the strong procedure.  EMPLOYEE(S) NAME AND TITLE (Pint or Type) DATE ISSUED AND TITLE (Pint or Type) Parts (1974) And CL. Silva, Investigate Investigate And CL. Silva, Investigate Investigate Investigate And CL. Silva, Investigate Investigate And CL. Silva, Investigate Investigate And CL. Silva, Investigate Investigate Investigate And CL. Silva, Investigate	Specifically,			
was opened on 7/17/08. The problem involved distribution of 23 red blood cell without ice to consignee. This issue also resulted in consignee being instructed to destroy the units by No hold was placed on the units. A corrective action was developed and implemented; and a 3 months effectiveness checks from September to November was implemented.  Observation 2  Written procedure was not followed regarding handling of "Management of Suspect Products".  Specifically,  On 3/20/08 and 7/17/08 (D(4)) and (D(4)) Hospital Services Supervisor (JO) instructed the consignees to destroy units, instead of referring the customer complaints to ARC, Dedham, MA for follow up, as it's written in ARCBS (D(4)) (A)  apply the appropriate hold or assertion and a specifical services supervisor (JO) instructed the consignees, Hospital Service Supervisor (JO) (A)  Apply the appropriate hold or assertion and the property of the customer complaints to ARC, Dedham, MA for follow up, as it's written in ARCBS (D) (A)  Apply the appropriate hold or assertion and the property of the customer to the customer complaints to ARC, Dedham, MA for follow up, as it's written in ARCBS (D) (A)  Apply the appropriate hold or assertion and the property of the customer to the customer complaints to ARC, D) (A)  Apply the appropriate hold or assertion and the customer to the customer complaints to ARC, D) (A)  Apply the appropriate hold or assertion and the customer to the customer complaints to ARC, D) (A)  Apply the appropriate hold or assertion and the customer to the customer complaints to ARC, D) (A)  Apply the appropriate hold or assertion and the customer to the customer complaints to ARC, D) (A)  Apply the appropriate hold or assertion and the customer to the customer complaints to ARC, D) (A)  Apply the appropriate hold or assertion and the customer to the cu	red blood cells without ice to a consignee. This was a (b) (4) investigation. The consignee was instructed to destroy the units by Hospital Services Supervisor referred (JO). No hold was placed on the units. A corrective action, and a three months effectiveness check from June to August were developed and implemented. On 9/9/08 during QA review of (b) (4)			
Written procedure was not followed regarding handling of "Management of Suspect Products".  Specifically,  On 3/20/08 and 7/17/08 (b) (4) and (b) (4) Hospital Services Supervisor (JO) instructed the consignees to destroy units, instead of referring the customer complaints to ARC, Dedham, MA for follow up, as it's written in ARCBS (b) (4) (b) (4) (b) (4) (b) (4) (c) (d) (d) (d) (e) (d) (e) (e) (f) (f) (f) (f) (f) (f) (f) (f) (f) (f	occurred; an exception (b) (4) was opened on 7/17/08. The problem involved distribution of 23 red blood cell without ice to consignee. This issue also resulted in consignee being instructed to destroy the units by No hold was placed on the units. A corrective action was developed and implemented; and a 3 months effectiveness checks from September to November was implemented.			
Specifically,  On 3/20/08 and 7/17/08 (b) (4) and (b) (4) Hospital Services Supervisor (JO) instructed the consignees to destroy units, instead of referring the customer complaints to ARC, Dedham, MA for follow up, as it's written in ARCBS (b) (4)  (b) (4) (b) (4) (c) (d) (d) (d) (e) (d) (e) (e) (f) (f) (f) (f) (f) (f) (f) (f) (f) (f	Observation 2			
On 3/20/08 and 7/17/08 (b) (4) and (b) (4) Hospital Services Supervisor (JO) instructed the consignees to destroy units, instead of referring the customer complaints to ARC, Dedham, MA for follow up, as it's written in ARCBS (b) (4) (b) (4) (c) (d) (d) (d) (e) (d) (e) (e) (e) (f) (f) (f) (f) (f) (f) (f) (f) (f) (f	Written procedure was not followed regarding handling of "Management of Suspect Products".			
the consignees to destroy units, instead of referring the customer complaints to ARC, Dedham, MA for follow up, as it's written in ARCBS (D)(4)  (b)(4)  apply the appropriate hold or assertion (b)(4)  apply the appropriate hold or assertion (b)(4)  In both cases, Hospital Service Supervisor (D)(6) was not following procedure.  SEE REVERSE OF THIS PAGE  EMPLOYEE(S) SIGNATURE  ATHOLY N. ONIANWA-Investigate  ATHOLY N. ONIANWA-INVESTI	Specifically,			
ANTHONY N. ONIANWA-Investigator OF THIS PAGE QC & Alice C. Silva, Investigator 10 24108	the consignees to destroy units, instead of referring the customer complaints to ARC, Dedham, MA for follow up, as it's written in ARCBS (b) (4)  (b) (4)  apply the appropriate hold of assertion apply the appropriate hold of assertion both cases, Hospital Service Supervisor (b) (6) was not following procedure.			
	REVERSE OF THIS PAGE	Hice C. Silva, Investigator 10/24/08		

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION		
1 Montvale Avenue	11/12-24/08		
Stoneham, MA 02180	FEI NUMBER		
781-596-7700	1273014		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  TO: Paul T. Sullivan, CEO			
FIRM NAME	STREET ADDRESS		
American Red Cross Blood Services CITY, STATE AND ZIP CODE	209 Farmington Avenue TYPE OF ESTABLISHMENT INSPECTED		
The state of the s			
	Licensed Blood Establishment		
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.			
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:			
Observation 3:			
Failure to sign and date equipment validation/revalidation records.			
Specifically,	*		
Equipment ID's: (b) (4) not sign/date; and the work order closed dates were not documented on the equipment problem/deficiency reports. According to ARC CT Blood Service local operating procedure, (b) (4) titled (b) (4) requires that equipment validation be signed and dated, and work order closed date be documented.			
* «			
74.			
	•		
4			
8			
,	•		
SEE EMPLOYEE(S) SIGNATURE REVERSE	PLOYEE(S) NAME AND TITLE (Print or Type) LICE C. Silva, Investigation  Date issued		
OF THIS PAGE	nthon, N. Orignus - Trestrator 11/24/2008		
FORM FDA 483 (4/03) PREVIOUS EDITION OBSOLETE INSI	PECTIONAL OBSERVATIONS PAGE 2 OF 2 PAGES		