TRENT REGIONAL TRANSFUSION CENTRE

QUALITY ASSURANCE LABORATORY

STANDARD OPERATING PROCEDURE NO. QA 866-90-02

RECALL PROCEDURE QUALITY ASSURANCE

FOR BLOOD & BLOOD DERIVATIVES

9/6/93 SPECIMEN FOR PORTUGESE MO

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Recall Procedure Quality Assurance

1. Introduction

1.01 A Recall may be necessary following reports of problems by suppliers, customers or departments within the Regional Transfusion Centre.

1.02 A decision on the significance of the problem and whether or not a recall is necessary must only be made by a senior member of staff in consultation with the Director or Consultant Medical Officer and the Q.A. department.

1.03 The Q.A. department must be informed of and co-ordinate all recall procedures.

1.04 In the absence of all medical officers the Q.A. staff may need to consult with the National Directorate.

1.05 Other staff receiving a complaint or aware of a problem must refer it to the staff in 1.02.

Recall forms I TRTC535 and II TRTC536 can be obtained from the Director, Q.A. Department or Dr. Forman.

After the recall is completed the Forms and any related documents should be returned to the QA department.

1.06 Accountability for all products is essential. To ensure that all relevant information is obtained and recorded Form TRTC 535, must be used. Sample in Appendix I.

1.07 Depending on the complexity of the problem it may be necessary for a separate second form to be followed for contacting every external organisation. Recall Form II TRTC 536. Sample in Appendix II.

1.08 It may be necessary to involve the National Directorate, or the Department of Health. This decision should be made by the Director, Consultant Medical Officer or Q.A. staff if neither of these is available.

1.09 We should subsequently contact hospitals NOT directly affected if it is likely they may hear of the incident from another source.

1.10 Withdrawal of product due to a simple donor illness affecting the current donation only, can be performed by any Medical Officer or Head of Laboratory, using the incident report form to provide a record of the action taken.

1.11 Internal incident forms TRTC 515 (Appendix V) are available throughout the centre.

2. Safety/Precautions

2.01 Even if future use is unlikely ensure storage conditions are maintained during quarantine.

2.02 Ensure all products "in Transit" are located.

2.03 A decision must be made regarding disposal or re-release of material by a Consultant Medical Officer in conjunction with Q.A.

2.04 For some donations there are multiple identical products for the same donation number.

2.04.01 Autopheresis C trial plasma wedges bled October 91 to January 92. See Appendix VI.

2.04.02 Paediatric FFP.

2.05 The autopheresis C plasma has been sent to BPL.

Paediatric FFP donations with identical donation numbers are issued simultaneously to one hospital.

2.06 Despatch staff and drivers must be fully informed of the need to clearly label and segregate any products returned from hospitals.

2.07 If the recall involves blood collection packs, the record of the reserve stocks in the Alfreton depot and of packs issued to hospitals for their own use must be checked for the lot number(s) concerned.

3. Materials

3.01 Recall Form I (TRTC 535). Recall Form II (TRTC 536) available from the Director, Q.A. department or Dr. Forman.

3.02 Lists of names and telephone numbers in the appendices of this S.O.P.

3.03 The assistance of the computer department may be required.

3.04 Quarantine labels "NOT FOR ISSUE" (available from QA or Director).

4. Recall of Blood or Blood Derivatives from Sheffield R.T.C

If the computer has recently been down, records of manual issues during this period must be searched.

4.01 Record information on recall Form 1 TRTC 535 stating reason for recall.

4.02 Obtain donation number(s) or donor identification information.

4.03 Interrogate the computer to obtain full details on each donation.

4.03.01 Date bled and session.

4.03.02 Identify all derivatives prepared and any plasma donations in Batches for Bio Products Laboratory (Elstree).

4.03.03 Check the current whereabouts of all derivatives. These may have been issued to - Hospitals, Bio Products Laboratory, Other Regional Transfusion Centres or used for research. They may also be "IN STOCK" being tested or processed, in transit or may have been entered as expired or reject units.

4.03.04 A record of the batch numbers relating to filtered units will be found under the date of preparation in the Work Record Book in the Blood Products Laboratory.

4.03.05 A record of batch numbers relating to bone marrow preparation will be found in the marrow file, second drawer of the filing cabinet in the office of the Products Laboratory.

4.03.06 If the computer shows "Paediatric FFP unit" there will be two units both with the same donation number. These are only issued together to the the same hospital.

4.03.07 During the period of the Autopheresis C Trial each donation collected produced two wedge packs with the same donation number. These were given an SB suffix to the batch code.

If it is necessary to recall any such products two wedges must be traced.

4.04 Any donations and derivatives in stock must be located on site and quarantined. All items should be labelled "NOT FOR ISSUE". Do not store in proximity to material available for issue.

Donations and derivatives requiring 4°C storage should be clearly labelled and transferred to Blood Products Cold Room No 67.

4.05 When contacting the recipients of any issued donations and derivatives Form II (TRTC 536) must be used to ensure a standard procedure is followed.

The use of the FAX machine may be helpful for transmitting lists of numbers.

4.06 Ensure the driver and despatch staff who may be handling recalled donations and derivatives are fully informed and aware of the action required of them.

4.07 Therapeutic material returned from hospitals must not be re-issued.

4.08 If any plasma has been prepared into batches for Bio Products Laboratory the Head of Blood Products laboratory / Dr Forman, or their deputies are responsible for contacting the Bio Products Laboratory. This may be done by telephone, fax and followed up by a letter.

4.09 Appendix III of this S.O.P lists all telephone numbers of Hospital Blood Banks supplied by the Sheffield Regional Transfusion Centre, the names of the Consultant Haematologist and head of the Blood Bank Laboratory.

4.10 Appendix IV lists telephone numbers of all other Regional Transfusion Centre Directors and Quality Assurance Managers.

4.11 Explain the problem to the contact person at Hospital/other Regional Transfusion Centre. Record the name of the person contacted on Form TRTC 536.

4.12 Arrange quarantine and return of all unused donations and derivatives. Give the name of a person to whom they must be addressed.

4.13 Establish the urgency of any replacements which may be required. Make transport arrangements.

4.14 Ask the recipient to obtain details related to any donations or derivatives which they have used.

4.15 It is important that all derivatives are traced and accounted for. List any 'missing' derivatives/donations for further investigation into their whereabouts.

4.16 Inform other staff within the Regional Transfusion Centre of the problem.

4.17 If it is considered necessary inform the National Directorate, and the Department of Health.

5. Blood Donations from other Regional Transfusion Centres

5.01 Donations received from other Regional Transfusion Centres are NOT entered into our computer system.

5.02 Records of receipt and issue of such donations are kept in the despatch office filing cabinet under 'IMPORTED BLOOD'.

5.03 Following issue of any of these donations and identification of their destination by examination of the written records the same procedure for recall should be followed, Using forms TRTC 535 & 536.

6. Products from Bio Products Laboratory (Therapeutics)

6.01 This section contains information on records and issue information pre & post 1st April 1991:-

Pre & Post April 1991		Pre April 1991
4.5%	Albumin	Factor VIII
20%	Albumin	Factor IX
2,500 I.U.	IgG anti-D	250 & 500 iu doses IgG anti-D
		Other Immunoglobulin injections

6.02 In the event of a recall from Bio Products Laboratory, the Director, Dr Forman, Blood Products or Quality Assurance personnel will be contacted by Bio Products Laboratory.

6.03 Records related to the issue of all B.P.L. products by the Regional Transfusion Centre, are kept by the despatch office staff. The issue sheets are filed in datal order by the despatch clerical Officer. Current copies in the office, older copies in the "void" storage area. The Main Despatch Ledger records Batch numbers of products issued to individual hospitals.

6.04 From 1st April, 1991 products from BPL (T) have been issued directly to hospitals by BPL. The RTC acting only as a carrier.

6.05 On receipt from Bio Products Laboratory products are stored at the required temperature in cold room 77 and on the loading bay prior to despatch to the appropriate hospital.

6.06 'Parcel' delivery notes only will be used to provide evidence of carriage between the RTC and hospitals.

6.07 The RTC will continue to be responsible for storing and issuing a relatively small volume of contingency stocks of BPL albumin for use in emergency situations only. This will be stored in fridge 77 and stores.

6.08 The despatch office will keep records relating to receipt and issue of RTC contingency stocks.

6.09 The RTC will continue to hold stocks of 2500 iu IgG anti-D injections for the Region.Information on their issue will be sent to BPL.

6.10 On receipt of information from Bio Products Laboratory relating to our contingency stocks of 2500 iu doses of IgG anti-D form TRTC 535 should be followed to investigate the recall and form 536 used when contacting every customer we have supplied, NB There may be items in 'Transit'.

6.11 Information regarding batch numbers, quantities and dates issued must be obtained from despatch and entered on form TRTC 535.

6.12 If the recall relates to a batch of IgG anti-D, records of the batch numbers issued to the majority of Sheffield patients prior to May, 1991 will be found in the Kleihauer Laboratory. The exception is the 250 iu doses issued to Northern General Hospital Blood Bank. These records were kept by despatch. After May, 1991 the only issue records kept by despatch will be for 2500 iu doses.

6.13 When contacting the hospitals follow the procedure relating to quarantine/return, replacement, accounting for all units as in section 4 of this SOP. Some may have been issued by hospitals to other users.

6.14 Stocks which are located at the Regional Transfusion Centre should be isolated from the products available for issue and clearly labelled "NOT FOR ISSUE" while awaiting information re their disposal or future use.

This decision must be made by the Director or Consultant Medical Officer.

6.15 Even if future use is unlikely, ensure storage conditions are met.

6.16 If it is necessary to trace the use of batches of lignocaine or specific lot numbers of blood packs this information can be obtained from the micro computer in the QA department and the sessional report sheets.

7 Equipment and Materials with donor/donation product implications.

7.01 Section 7 lists these products and their likely whereabouts.

7.02 Follow Recall Forms TRTC 535 & 536 to ensure that all action required to recall a product is carried out.

SECTION 7

PRODUCT & SUPPLIER (If known)	CODE	Blood Collection Packs (BAXTER)	Apheresis Harness (Haemonetics)	Apheresis Anticoagulant (Birmingham) SSU	Cannula (Avon Medical Ltd)	Lignocaine Xylocaine (Phoenix Pharmaceu-ticals)
		Single Packs	Various According to Machines in use	CPD 50	R700I	
		Various Other Pack Types		Acid CPD		
				ACD A		
STORES		*	*	*	*	*
BLOOD PRODUCTS						
DESPATCH						
DONOR ATTENDANTS MOBILE ASSEMBLY		*				*
WESTFIELD HOUSE		*	*	*	*	*
LEICESTER PLASMA			*	*	*	*
SESSIONS/TRANSIT		*	*	*	*	*
HOSPITAL BLOOD BANK		*				
PRODUCTION UNIT						
ALFRETON RESERVE		*				
LEICESTER & NOTTM RESERVE		*				
FIRST AID ROOM						
OTHER						

* Where items are located

SECTION 7

PRODUCT & SUPPLIER (If known)	Methoxamine Hydrochloride (Vasoxine) (Wellcome Calmic Div	Emergency Drug Tray NGH Pharmacy	Ca Gluconate	Piriton	Adrenalin	CODE
STORES	*					
BLOOD PRODUCTS						
DESPATCH						
DONOR ATTENDANTS MOBILE ASSEMBLY	*					
WESTFIELD HOUSE	*	*	*	*	*	
LEICESTER PLASMA	*	*	*	*	*	
SESSIONS/TRANSIT	*					
HOSPITAL BLOOD BANK						
PRODUCTION UNIT						
ALFRETON RESERVE						
LEICESTER & NOTTM RESERVE						
FIRST AID ROOM						
OTHER						

* Where items are located

SECTION 7 PRODUCT & SUPPLIER (If known)	CODE	STORES	BLOOD PRODUCTS	DESPATCH	DONOR ATTENDANTS MOBILE ASSEMBLY	WESTFIELD HOUSE	LEICESTER PLASMA	SESSIONS/TRANSIT	HOSPITAL BLOOD BANKS	PRODUCTION UNIT	ALFRETON RESERVE	LEICESTER & NOTTM RESERVE	FIRST AID ROOM	OTHER
Gambro Bags	2XDF-700-3		*											
Acrodisc Filter	6724192		*											
Sampling Site Coupler	C1401		*											
DMSO	D2650		*											
Hanks	18-100-54		*											
Heparin	74301		*											
L. Glutamine	16-801-49		*											
Kwill Filling Tube	E910 5"		*											
Transfer Lines	2243		*											
	2240		*											
	2244		*											
Transfer Packs	R2021	*	*											
	FRR2012	*	*											
	RPR2022	*	*											
	FKR2041	*	*											
Viaflex IV	FKB1322 250 ml	*	*											
	FKB1323 500 ml	*	*			*	*	*						
	FKB1324 1000 ml	*	*											
Leucocyte Filters	B2131		*											

* Where items are located

SECTION 7 PRODUCT & SUPPLIER (If known)	CODE	STORES	BLOOD PRODUCTS	DESPATCH	DONOR ATTENDANTS MOBILE ASSEMBLY	WESTFIELD HOUSE	LEICESTER PLASMA	SESSIONS/TRANSIT	HOSPITAL BLOOD BANK	PRODUCTION UNIT	ALFRETON RESERVE	LEICESTER & NOTTM RESERVE	FIRST AID ROOM	OTHER
Sample Containers		*		*	*	*	*	*					*	
Copper Sulphate BDH	36204 36202	*			*	*	*	*						QA
Lancets		*			*	*	*	*						
Needles		*			*	*	*	*			*		*	
Syringes		*			*	*	*	*					*	
Mediwipes		*			*	*	*	*						
Molnlycike Swabs	584000	*			*	*	*	*						
IV Drip Sets (Giving Sets) Travenol	C2055	*				*	*							
Dressings		*			*	*	*	*						
Lint Squares		*												
Gauze Swabs		*			*	*	*	*						
Plasters		*			*	*	*	*						
Sterettes		*			*	*	*	*						
Autolets		*			*	*	*	*						

* Where items are located