NHS

MEDICINES INSPECTORATE

(BLOOD TRANSFUSION CENTRE) INSPECTOR'S SUMMARY

FILE REF: 285/IN/ | MB5B Report No. 1989 / 14-47

TITLE: INSPECTION OF NORTH LONDON REGIONAL BLOOD TRANSFUSION CENTRE, COLINDALE AVENUE LONDON NW9 5BG

CO. TEL: 01-200 7777

DATE OF INSPECTION: 23-25 MAY 1989

INSPECTOR(S): M L KAVANAGH

REGION/AREA (9.1) _ _
GMP ( ) _ _ HAZARD INTVL (12) _ _
CATEGORY (HP) _ _
NO. EMPLOYEES ( ) 290 COMPLEXITY add / delete _ _ _ _ _

COPIES TO:

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	For routine distribution		M. Bunton
	DR H H GUNSON		Mrs Lewson
	Mr Green		

DATE OF PREVIOUS INSPECTION:

PURPOSE OF VISIT:

FIRST INSPECTION OF NEW CENTRE

LICENCES HELD OR APPLIED FOR:

LICENSING CHANGES: ACTUAL:

IMMINENT:

RECOMMENDATIONS/ACTION:

1. A COPY OF THIS REPORT TO BE SENT TO THE REGIONAL HEALTH AUTHORITY FOR COMMENT AND PROPOSED ACTION.
2. FOLLOW-UP INSPECTION WHEN CLEAN ROOM FACILITIES AND PROCEDURES CORRECTED.
3. FULL RE-INSPECTION WITHIN 2 YEARS.

COMPILED BY: GRO-C
M L KAVANAGH

DATE SIGNED: 4 August 1989.

COUNTER SIGNATURE:
REGIONAL PMI

SMI GRO-C 4/8/89

HEAD OF MEDICINES INSPECTORATE

The factual matter contained in this report relates only to those things that the Inspector(s) saw and heard on the occasion of the visit. This report is not to be taken as implying a satisfactory state of affairs in premises, equipment, personnel or procedures not examined on this occasion.

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1. INTRODUCTION

North London Blood Transfusion Centre (NLBTC) is situated in a new, purpose-built building in the grounds of Colindale Hospital, most activities having been transferred from the old Centre in Deansbrook Road, Edgware, in March 1989. (An apheresis and routine donor clinic is still maintained at Edgware.)

The area served by NLBTC has a population of approximately 3.4 million and takes in 4 teaching and a number of postgraduate hospitals. About 196,000 whole blood donations and 20,000 plasma donations are collected annually. Approximately 360 staff, including part-timers, are employed (approx. 290 full-time equivalents).

The new Centre has not previously been inspected.

2. SCOPE

The inspection covered the manufacture and control of the products listed in Section 4. Clinical matters, eg tissue typing and testing related to patients, were not included.

3. SENIOR STAFF LIST

Dr M Contreras	-	Director
Dr P Hewitt	-	Deputy Director
Dr B Brozovic	-	Consultant Haematologist
Dr M de Silva	-	Consultant Haematologist
Dr S Knowles	-	Consultant Haematologist
Dr G Schwarz	-	Associate Specialist, Tissue Typing
Dr J Barbara	-	Top Grade SO, Microbiology
Mr A Martina	-	Regional Donor Organiser
Dr D Fehily	-	Senior SO, Components Laboratory
Mr S Penny	-	Senior SO, Components Laboratory
Mr R Knight	-	MLSO 4, Grouping Laboratory
Dr M Seghatchian	-	Principal SO, Quality Assurance Laboratory
Mr N Hogg	-	Principal SO, Data Processing
Dr A Lubenko	-	Principal SO, Immunology

4. LIST OF MEDICINAL PRODUCTS

Whole blood
Plasma-reduced blood
Concentrated red cells
SAG-M red cells
Cryoprecipitate-poor blood
Frozen/thawed red cells
Filtered blood
Washed red cells
Platelet concentrates (from routine donations and by apheresis)
CMV-negative platelets
HLA-typed platelets (apheresis)
P1 (A1 negative) platelets
Cryoprecipitate
Fresh frozen plasma (FFP)
Paediatric FFP
FFP for fractionation at BPL
Time-expired plasma for fractionation at BPL
Hyperimmune plasma for fractionation at BPL
CMV-negative blood
Phenotyped blood.

5. INSPECTION

5.1 Blood Collection and Receipt

Blood collection take place at 28 mobile sessions per week, including 5 using the special "Bloodmobile" truck, in addition to the static donor clinics at Deansbrook Road, Edgware, the West End Donor Centre in Margaret Street and in Luton. A visit was made to a mobile session held in the social club of the Shredded Wheat Factory, Welwyn Garden City.

Although the introduction of a computerised system of donor records is planned for later this year, the system currently in use is that of colour-coded cards. The record cards for all the donors on the appropriate panel are brought to each session; new donors are provided with buff-coloured cards.

At the clerking table, when a donor has completed the medical checklist and consent form, a set of 8 bar-code labels is issued together with bar-coded group labels for the blood packs. The donor's name and group are manually recorded on the Bleed Sheet and 2 of the 8 bar-coded donation number labels are attached. (Labels for new donors have pink edges.) The donor is then given his or her record card, together with the 6 remaining bar-code labels and the group label, and proceeds to the haemoglobin-testing table.

Haemoglobin testing is done using the copper sulphate method, the limits of acceptance being 125g/litre for females and 135g/litre for males. If a donor fails the copper sulphate test, a repeat test is performed using a haemoglobinometer. (Approximately 30% of donors failing the copper sulphate test subsequently pass on the haemoglobinometer). If donors fail the haemoglobinometer test, they are referred to their GP, unless they are women of child-bearing age with a haemoglobin level of not less than 120g/litre, in which case they are given an explanatory leaflet. If the haemoglobin level is less than 110g/litre for males and less than 100g/litre for females, donors have a venous sample taken for full testing back at the Centre.

At this stage, donors are given the opportunity of confidentially identifying themselves as members of high risk groups for AIDS. This system is unique to NLBTC and involves the donor ticking "yes" or "no" on a questionnaire asking them if they belong to one (or more) of 7 defined risk groups. The questionnaire is ticked in a "polling booth" type cubicle and is posted into a "ballot box". One of the main advantages of this procedure is that a donor in a risk group, if he/she feels it is impossible not to donate, can identify the donation which can subsequently be removed and not used to treat patients.

Accepted donors are led to a bleed-bed by a donor attendant (DA), re-identified against their record cards and prepared for donation. A mobile team usually consists of 8 DAs (sufficient for 1 per bed plus 1 extra), 2 Team Leaders and 2 drivers. A Team Leader issues the appropriate pack according to the Clinic Sheet prepared by the Donor Office. (At this particular session, the Team Leaders' table was very cluttered with boxes of packs, bags of equipment, rolls of sellotape etc.)

Venepunctures are performed by the MO, lignocaine not being routinely used. When the donation is under way, the DA labels the pack and the two (one wet, one dry) sample tubes, excess bar-code labels being stuck on the back of the main pack. Should a sample-tube be dropped and broken after labelling (but before the sample is taken), a new tube would be labelled using a spare from the back of the pack.

At the end of the donation, the samples are taken and the pack is stripped (at the bedside) and clipped off before being taken, together with the donor's record card, to the driver, who periodically puts crates of blood into the transport vehicle. Temperature control and monitoring of the vehicles is unsatisfactory. The specification for the temperature required is 0° - 26°C, drivers being required to note the dial reading at the beginning and end of sessions. The dials were last calibrated in December 1988 but the "refrigerators" are in reality cold-boxes into which cold plates are inserted during the summer months. Blood for platelets (the majority) and also donations to be used as whole blood are stored in the cold box together. At the time of inspection, the dial reading was 13°C.

There are no SOPs for donor sessions but there is a Procedures Manual, a copy of which is available to each team. Training of DAs is "on the job", followed later by a joint Training Day in the Centre. There is a check-list of duties in which each DA should achieve competence.

5.2 Components Laboratory

When a driver returns with blood, he writes the time of arrival and his initials onto a log-sheet on the notice-board outside the Components Laboratory. The "ballot box" of AIDS questionnaires is collected by Questionnaire Clerks who check the forms to identify any "risk" units. Meanwhile, the packs are wanded into the computer (donation number, group and pack-type) to set up the data base. However, processing does not start until the Questionnaire Clerk has confirmed that there are no risk units present. If there are risk units, the clerk collects them, wands them to "hold" in the computer (with Components staff) and isolates them.

Blood is usually brought back and processed on the same day but blood from the few evening sessions is stored overnight at 4°C and processed the following morning. Platelet concentrates made from this blood are known to be inferior to those prepared from non-refrigerated blood but their use is necessary to meet demand.

The Blood Sheets from the sessions are photocopied, one copy being retained in Components, one going to Microbiology and the original going to the Grouping Laboratory. Packs not to be processed are isolated at the time of wanding and are indicated on the Bleed Sheet with a cross.

The main processing area of the laboratory is equipped with 4 x Beckman J-6 Ms, 2 x J-6MEs and a number of J6s and J6Bs. At the time of inspection, the laboratory was very warm and the windows were open, allowing the ingress of insects and dust. Wide ledges in front of the windows and behind the centrifuges were dirty and dusty. In general, the laboratory is not well-designed for its purpose, being equipped with high-level wiring gantries which are dirt and dust traps. At present, they are not part of the cleaning schedule. The floor was also dirty.

There are no written, scheduled cleaning procedures for laboratory benches or items of equipment such as plasma extractors and centrifuges. No logs are kept of clean-down procedures. Staff are said to be "encouraged" to wipe the benches with disinfectant at the end of each day.

The pooling of fresh plasma into 5L packs (for freezing and despatch to BPL) is an open process and is carried out in one of three Microflow LAF cabinets in an area off the main laboratory. Staff performing the pooling wear their normal laboratory clothing with the addition of non-sterile gloves; masks and head covers are not worn. At the time of inspection, an external window near the LAF cabinet was open. There is no written procedure for cleaning the LAF cabinets and the cleaning is not logged. There was a layer of dust on top of the cabinet.

The 5 litre pools of plasma for fractionation, together with FFP both for BPL and for clinical use, are frozen and temporarily stored in two Cryo King Ultralow freezers, situated in another area off the main laboratory. One of these freezers was out of commission at the time of inspection. Although the freezers contain material for clinical use, they are not wired to the alarm system; however, the temperatures are checked and logged daily by QA. The weekly circular chart record was totally illegible, having not been changed since the freezers were installed on 20th March.

Any packs that burst during processing are disposed of by the Primary Control SO. Components staff deliver the packs but receive no receipt or record of the delivery. The Primary Control SO subsequently logs the packs, records the defect for each one, disposes of them and enters them into the computer as discarded. The record of such discards is inadequate, being very untidily kept, with ticks supposedly meaning that the action has been recorded in the computer not always being entered.

All frozen products awaiting clearance for issue are held in a bank of chest and upright freezers in a separate Freezer Room. All these freezers are wired to the central alarm system but at the time of inspection this was not yet fully operational (see Section 5.5).

Platelet concentrates are held in 4 multi-tray shaking incubators at 22 ± 2°C, which are also alarmed. One of the incubators is used for "held" platelets. Platelets are not produced from new donors.

The Components Laboratory has a set of newly completed SOPs although it was said that it was never necessary to use them. There are also Training Logs for each member of staff.

For historical reasons, open processing other than plasma pooling is done, rather illogically, by Biochemistry department staff rather than Components Laboratory staff. The procedures involved are the preparation of frozen and thawed red cells, washed red cells and filtered blood and are carried out in the "sterile suite". At the time of inspection, this had not been accepted as commissioned because of a number of problems, not least the fact that the temperature inside ranged from 26 - 30°C. Nonetheless, the area was being used for open processing.

Although called the sterile suite, the processing area is a clean room entered via a single change room. The room is supplied with HEPA-filtered air and is designed to be at overpressure to the change room which in turn is at overpressure to the main laboratory. Two walls of the room are fitted with benches with overhead vertical LAF. A number of design faults are apparent; the fronts of the overhead LAFs are fitted with projecting Magnahelic gauges, switches and wires; ordinary 13 amp electric sockets are fitted along the walls under the LAF; the door to and from the change room has a closer, exposed hinges and an ordinary door handle; the fire-escape door has a standard push-bar fitment; the doors of the change rooms are not interlocked.

Staff working in the clean room enter via the change putting on a clean jacket, headcover and dedicated shoes. Outdoor trousers (or jeans) are not covered and masks and gloves are not worn. At the time of inspection, writing up of paperwork was being carried out on the bench under the LAF during processing and a large amount of unnecessary equipment was in the room.

5.3 Grouping Laboratory

The Grouping Laboratory is responsible for routine donor testing. In addition, there is a cell typing/reagents section and a Reference Laboratory. The department is equipped with a Kontron Groupamatic 2000 mk II and a Microgroupmatic system. Reagents for both automated and manual grouping are prepared and standardised here.

Samples from sessions, having been delivered to the Components Laboratory, are collected by Grouping Laboratory staff. New donor samples are set aside for grouping the following morning, while known donor samples are centrifuged and loaded onto the Kontron Groupamatic. The reagents for the machine are calibrated twice daily, in the morning and afternoon. The Groupamatic reads the bar-coded donation numbers on the side of the tubes and prints out the grouping results.

Results which the machine is unable to interpret are interpreted by eye and entered manually into the computer. (If a result cannot be interpreted by eye, then grouping is repeated on the machine or, if necessary, manually). Each session is given a batch number and the hard copy of the results is signed by the operative and retained for 12 years.

The results from the Groupamatic are transferred by direct link from the dedicated PC to the main frame computer. (The diskette of the PC is retained for 1 month). The main computer automatically compares these results with the group information wanded in by Components staff from the labels applied at the session. The computer will, on request, list any "errors", ie disagreements. Hard copy is obtained and the computer is currently programmed such that existing records are changed to the new result immediately, deleting the error and enabling the process to continue. Errors are subsequently investigated, regrouped if necessary, and edited into the record. Access to the computer for editing is controlled by a bar-coded password but this is available to four staff members and does not identify individuals making entries (other than the manual entering of personal initials).

New donors are grouped on the Kontron Microgroupamatic machine, which is based on a Microtitre plate format, results being produced on a print-out in a similar way to the Groupamatic 2000. All new donors are grouped twice on the same machine but using different Rh reagents. The machine compares the two sets of results, discrepancies being repeated manually. Results are then transferred to the main computer.

Full donations from new donors which lack a sample tube are manually grouped twice on a sample taken from the pack bleed line, using different Rh reagents each time. Manual grouping results are written onto Results Sheets, which are totally inadequate as records. The printing is illegible and the examples seen at the time of inspection contained numerous unsigned alterations, including several date changes, and many Tippex alterations.

The results of the two manual groupings performed by two MLSOs are compared by a third person and the results are typed into the computer by one of them. These entries are checked by an independent person, who types in the relevant donation numbers and compares the groups displayed on the VDU against the Results Sheet. When the results have been transferred onto the 101 cards, these are checked against the protocol by a senior MLSO.

5.4 Microbiology

All samples are tested here for HBsAg, HIV antibody and syphilis (TPHA). Samples are tested for HBsAg using both the Fujirebio haemagglutination test and BPL RIA, the latter being more specific and sensitive than the haemagglutination test, giving approximately 5% difference in pick-up rate. For new donors, no products can be released until results of both tests are available; for previously tested donors, products (ie platelets) can be issued on the strength of the haemagglutination test only, giving rise to a theoretical slight risk to patients.

HIV antibody testing utilizes the Wellcozyme ELISA technique and the syphillis TPHA is a modified Fujirebio. In addition to these tests, approximately 40% of donors are tested for CMV (modified Beckton Dickinson latex test) and smaller numbers of samples are tested for Toxoplasma, malaria antibody and hyperimmunity to tetanus, hepatitis B, Varicella-zoster and CMV. On average, the department handles 900 samples per day, requiring 4000 tests. A small amount of QC bacteriology is also undertaken (see Section 5.5).

Donor samples are collected by microbiology staff together with the Bleed Sheet stubs, which carry the corresponding donation numbers. The samples are checked against the stubs, the numbers of missing samples being crossed off, and the tubes are arranged in numerical order in Microtitre format racks. The appropriate rack identification number (A1-4, B1-4 etc) is marked against the donation numbers on the Bleed Sheet stubs and the racked tubes are centrifuged.

After centrifugation, samples are pipetted out manually onto master Microtitre plates, 4 racks equating to 1 plate. The pipetting is performed with a 6-tipped Finn pipette, one person pipetting while a second person sets up the tips and checks the procedure. The Microtitre plates are identified by marking on a number and the date. 2 plates are set up, 1 for HIV antibody assay and one for HBsAg RIA, each well containing 200 µl.

For HIV antibody assay, 50 µl volumes are sampled from the master plate into the ELISA plate by means of a Transplate 96 machine. (The remaining 150 µl volumes in the masterplate are kept frozen as library samples, the plan being to retain them for 11 years). For the ELISA test, the kit controls and the standards supplied by CPHL, Colindale, are included in every plate. In addition, a panel of 6 controls supplied by CPHL is set up daily. For the HBsAg RIA, the BPL standards are run each time.

Plates for TPHA and HBsAg haemagglutination assay are set up by subsampling from the original racked sample tubes using a mechanical sampling device designed and constructed at NLBTC. The control for TPHA is an in-house known positive with a cut-off of approximately 1:32 and for HBsAg HA it is a 1:16 positive in-house control, each batch of which is controlled against a ng standard.

Reactive wells in each test are recorded on a Results Sheet using a well identification code. From this, using a hand-written master decoding sheet, the well can be related to a rack number and position and hence the sample donation number. All this information is recorded on the Results Sheet. This is a very manual procedure involving the transcription of well numbers, rack numbers and donation numbers. The Results Sheet seen at the time of inspection had unsigned alterations made using Tippex fluid.

Implicated samples are removed from the racks and repeat-tested in duplicate. If, on repeat, the duplicate samples test as negative, then (if the first result was a weak positive) the sample is returned to the rack and the first result is regarded as a false positive. There is the possibility of error if the incorrect samples tube (ie a genuine negative) is accidentally removed from the rack for the repeat test in place in place of the genuine weak positive. (A program in the computer which would verify identical sample numbers would avoid this).

Repeat positives, their bar-code label on the Bleed Sheet stubs having been highlighted, are entered as positive into the main computer. There appears to be some confusion as to the method of entering the donation number, the SOP calling for the wanding of the number from the Bleed Sheet, while some staff claimed to wand the number in from the sample tube label.

Whenever there is a clear positive reaction, the pack is immediately isolated and a sample is take directly from the pack for testing. Other repeat positive samples are confirmed by testing a pack sample and if this is positive the pack is isolated. Microbiology staff call up the donation number on the computer and thus identify all the associated components. Microbiology staff are responsible for collecting these. A sheet is about to be brought into use which will record this collection and which will include relevant signatures. Currently, records are kept of the microbiology positive serum and plasma packs that are held in the department. However, these are hand-drawn up, dog-eared loose sheets held in a clipboard. There are no records at all of the discard of the associated red cell components.

The Microbiology Laboratory in general is rather short of space considering the workload and the area is cramped and cluttered with equipment, samples, work sheets etc. At one end of the main laboratory area is a freezer room where a number of freezers are filled with a wide variety of materials. This storage arrangement is very disorganised; individual freezers are not labelled, shelves within freezers are not identified and there is no inventory of the contents.

In recognition of the inherent dangers in a manual system of sample handling and result reporting, a new automated sample handler, a Kemble Kemtech 1000 machine, has been acquired and is to be brought into use. This machine, which has a carousel which holds 88 samples, reads the bar-code numbers on the tubes and delivers aliquots into the wells of 2 or 4 master Microtitre plates. It is planned to eventually bar-code label the plates so that the machine will identify a unique sample number with a unique masterplate and position. Subsampling of the masterplates will still be done manually but will be done using a Microtitre plate format dispenser such as the Transplate 96. Ultimately, the machine will automatically transmit the results of positives into the main computer.

Training of staff in Microbiology is "on the job" and there are no formal training logs to indicate stages of competence achieved. SOPs are available but not all of them are up-to-date.

5.5 Quality Assurance

The Quality Assurance department at NLBTC was originally established (in the old Centre) in 1973. Dr Brozovic is the Consultant Haematologist with responsibility for QA. Currently, the department is understaffed, consisting of a Principal SO, one SO and one Laboratory Aid. A second SO has recently been appointed to take up duty from September 1989. The position of Quality Manager was recently advertised but the resultant interviews were unsuccessful. There are also vacancies for 2 part-time SOs, 1 each in microbiology and serology. In addition, a Scientific Officer operates outside the QA department in "Primary Control" (checking balances and haemoglobinometers, check-weighing packs, disposing of burst packs) reporting directly to the Director.

A certain amount of environmental monitoring is performed in conjunction with the Microbiology department. Viable particle counts using a Biotest air-sampler are taken at the plasmapheresis clinic and in the "sterile-suite" but no limits have yet been defined other than to investigate if the count exceeds 50.

The SOP calls for weekly sampling but the records seen at the time of inspection indicated that the last occasion was 3 weeks previously (4 May).

Settle plates (nutrient agar and blood agar) are also used in the suite, being exposed for 30 minutes by the staff working inside. The plates, which are brought in, are incubated for 48 hours at 25°C and 37°C respectively. Batches of plates are not routinely tested with positive controls. The action limits for the suite were set on 10 April 1989 and are: 0-4 CFU, no action; 5-9 CFU, repeat sampling; 10-20 CFU, close the suite, clean and resample. On 27 April 1989, 7 CFU were found but no action was taken. The records are not well kept, with several illegible comments written on them.

Non-viable particle counting is done on a 6 monthly basis by the Principal SO (QC) of the NW Thames Regional Pharmaceutical Service. A 6-monthly maintenance schedule is to be implemented.

No other environmental monitoring is undertaken at present, although there are plans to extend the viable particle counting to donor sessions. There is no swabbing of benches or centrifuge buckets in Components to verify the effectiveness (or otherwise) of cleaning procedures.

Temperature monitoring of fridges and freezers is done daily on a manual basis, the checks being recorded on loose, handwritten sheets. No action limits have been defined. The alarm system installed to monitor fridges and freezers consists of a control panel, with audible and visible alarms, and a microcomputer, sited in the QC laboratory, which prints out temperature readings from all concerned refrigerated equipment every 3 hours, using 4 probes per channel. The system, at the time of inspection, still needed to be fully validated and alarm levels needed to be set. The printout data is excessive, making its interpretation time-consuming.

The main part of the work of the QA department is quality monitoring of products. Red cell products are checked for volume by weight on 2% of packs sampled randomly. In addition, sterility checks using nutrient agar and blood agar plates (ie not a true sterility test) are performed in Microbiology on time-expired products or hospital returns. These products are also checked for pH, Hb, PCV and weight but there are no action limits and little use is made of this information. 3% of fresh packs are visibly examined daily for quality.

Platelet concentrates are tested (using time-expired platelets representing approximately 2% of production) for volume (specification 50-60 cc), platelet count ($>55 \times 10^9$ per unit), leucocyte count ($<0.12 \times 10^9$/unit) erthrocyte count ($<4 \times 10^9$/unit), pH (6.4-7.4) and HSR (>50%). Cell counts are performed on a HI-Technicon cell counter using Technicon standards. The machine is maintained on a service contract. Results show that cold-blood platelets (ie platelets prepared from blood which has been refrigerated at 4°C, see Section 5.2) have a platelet count reduced by approximately 10%, contain more aggregates and have much reduced bioavailability.

Apheresis platelets are 100% checked for platelet count (which is written on the pack) and sterility checked (with a sample taken from the bleed-line). As all such platelets are issued on a named patient basis, there is also the opportunity for clinical follow-up.

FFP and Cryoprecipitate preparations are checked for volume and Factor VIII:C, the latter being measured using a one-stage assay on a coagulometer. The specifications for cryo are a volume of 10-20 ml and >80 iu FVIII:C/unit. For FFP the FVIII:C specification is >0.7 iu/ml (>0.5 iu/ml for 18 hour plasma).

Each month the quality monitoring results are circulated on a QA report which summarises the percentage of samples falling outside specification. The reports are discussed at monthly meetings attended by QA, Components and the Director.

There is little input at present from QA in documentation production and monitoring, although it is hoped to move towards standardising the format of SOPs. Representatives from the various departments in the Centre and from the Regional Pharmacy Department have formed what is known as a "Product Liability Working Group" and this is being used to try and unify procedures and SOPs.

5.6 Blood Bank and Issue

Units which have completed their testing and are theoretically ready for issue are wanded into the computer against the "sort" programme. The donation number, group and product labels are wanded and if all are in agreement with the database then the pack is passed to Issue. If there is disagreement, the computer prevents issue of the pack unless it is manually over-ridden.

Orders for blood and products are either standing, regular orders or telephone orders. When hospitals 'phone in an order, a clerk notes the request on a notepad and then transcribes it onto a duplicate order form. The top (white) copy is given to the Issue department and the second (pink) copy is retained in the office.

The order is put together and all material other than BPL products are issued through the computer. The destination hospital code is entered (either by wanding from a menu card or by manually keying in) and all the pack information is wanded through. The computer checks that all is in order and records the issue, printing out a duplicate delivery note. The delivery note is signed by the person who has put together the order and a copy is retained. In addition to the computer record, issues are also recorded on a card-index (one card for each hospital) which is checked monthly against the computer record. For out-of-hours orders, all the duties are performed by drivers, who record their actions in a book.

The issue of BPL products is not through the computer and records are kept manually. These records are very badly and untidily maintained, the batch numbers of issued products not being recorded for Factor VIII, Factor IX and anti-tetanus immunoglobulin. In the albumin stock/issue record, the figures do not always tally.

6. FUTURE PLANNED CHANGES/DEVELOPMENTS

The computer system is being expanded to include donor records, and, eventually, the issuing of BPL products.

The manual handling and recording of microbiology samples is to be automated using a computerised liquid handling system.

7. MATTERS OF CONCERN

a. Temperature specifications for the transport of blood and products are not defined and the monitoring and control of the temperature in the transport vehicles is inadequate.

b. Some platelet concentrates are prepared from blood which has been stored overnight at 4°C, although tests show that this procedure yields an inferior product.

c. Windows in the Components Laboratory were open to the outside, allowing the ingress of insects and dirt.

d. Cleaning procedures are in need of review. Dirt was gathering on wide shelves behind the centrifuges and on the floors. High level wiring gantries are not included in the cleaning schedule.

e. There are no written cleaning procedures for benches, equipment and LAF cabinets and such cleaning is not regularly scheduled and recorded.

f. FFP is pooled into 5L packs in LAF cabinets by staff wearing normal laboratory clothing. At the time of inspection, a window was open nearby and there was a layer of dust on the top of the cabinet.

g. The record of the disposal of burst packs is inadequate and Components staff have no record of packs being delivered for disposal.

h. The Cryo King freezers for the freezing and temporary storage of FFP were not alarmed at the time of inspection and the 7-day chart recording had not been changed since its installation on 20 March.

i. The "sterile suite" has a number of design faults. In particular:

i. the fronts of the LAF cabinets are fitted with projecting Magnahelic gauges, switches and wires;

ii. standard 13 amp sockets are fitted on the walls under the LAF;

iii. the door from the change area has a closer, ordinary door-handle and exposed hinges, all on the clean side;

iv. the doors of the change area are not interlocked;

v. the fire-escape door has a standard push-bar;

vi. the temperature/humidity control is inoperative.

j. The current procedures in operation for performing open-processing in the sterile suite are unacceptable. Staff wear only a clean jacket over their ordinary clothing, together with a hat and designated shoes. Gloves, masks and clean-room trousers are not worn. Paperwork is carried out under the LAF and unnecessary items of equipment are present in the room.

k. Access to the computer for editing the database is not restricted by the use of individual, identifying passwords.

l. The Record Sheets for recording the results of manual grouping contain illegible text and examples seen carried numerous unsigned alterations, some made using Tippex.

m. There is no computer verification of the identity of samples taken for repeat testing following positive microbiology results.

n. The relevant SOP calls for the donation numbers of microbiology positives to be wanded into the computer from the Bleed Sheet but staff often wand the sample tubes.

o. There is no signed check by a second person that the correct donation numbers on the Bleed Sheet have been identified as the microbiology positives.

p. No record is kept of the red cell products discarded in Microbiology.

q. The storage freezers in Microbiology are disorganised and overfull; individual freezers and shelves are not labelled and there is no inventory of the contents.

r. Environmental monitoring of the "sterile suite" is haphazard; no action was taken when a settle plate produced 7 CFU, although the action level is 5 CFU, and air sampling had not been performed for 3 weeks when the SOP calls for weekly monitoring.

s. There is no swabbing or other bacteriological testing of surfaces and equipment in the Components Laboratory.

t. The alarm system for fridges and freezers generates an excessive amount of printed data. Alarm set-points had not been defined and the entire system required validation at the time of inspection.

u. The manually-kept records for the issue of BPL products are inadequate, often lacking batch numbers and containing discrepancies in the figures.

8. POST-INSPECTION SUMMARY

After the inspection, a discussion took place, attended by all the staff listed in Section 3, except for Dr Hewitt, Dr Schwarz, Dr Fehily and Dr Lubenko. The inspector commented favourably on the space and facilities available in the new building and commended the staff on the speed and efficiency with which the transfer had been conducted.

The deficiencies noted above (Section 7) were listed and discussed. The design faults of the so-called sterile suite were acknowledged but the inspector advised that, provided correct clean-room procedures were adopted, the facilities could prove adequate for the limited open-processing currently being undertaken.

9. CONCLUSIONS

1. The new Centre is a big improvement, in terms of space and general facilities, on the old Centre at Edgware.

2. Several of the problems highlighted result from the fact that only a short time has elapsed since the building was completed and the Centre transferred.

3. Correct clean-room procedures, including the wearing of full clean-room clothing, must be adopted if open-processing is to continue.

4. A review of all cleaning procedures is urgently required.

5. The QA department needs to be expanded, particularly with a view to increasing environmental monitoring and improving documentation, especially record-keeping.