DEPT. OF HEALTH - MEDICINES INSPECTORATE

INSPECTOR'S SUMMARY

SITE: NHS (BLOOD TRANSFUSION CENTRE) COMMERCIAL IN CONFIDENCE

FILE REF: 285/IN/500/598/H	MB5B Report No. 1990 / 14 - 57
TITLE: INSPECTION OF OXFORD REGIONAL BLOOD TRANSFUSION CENTRE OXFORD	CO. TELE: 0865 65711
DATE OF INSPECTION: 28-30 MAR 1990	INSPECTOR(S): DR M L KAVANAGH

REGION/AREA (9.1) _ _ CATEGORY (H) H _ GMP ( ) _ _ add
HAZARD INTERVAL (12) _ _ NO. EMPLOYEES ( ) 202 COMPLEXITY delete _ _ _ _ _

COPIES TO :			
MISG	For routine distribution		Mrs Robinson
	Dr H H Gunson		R/ Ayling
	Dr H Pickles		Mr. Burton

DATE OF PREVIOUS INSPECTION: 4-6 March 1987

PURPOSE OF VISIT:

LICENCES HELD OR APPLIED FOR:

LICENSING CHANGES: ACTUAL:

IMMINENT:

RECOMMENDATIONS/ACTION:

1. A copy of this report to be sent to the Director and to the Regional Health Authority for comment and proposed action.
2. Re-inspect within 12 months.

COMPILED BY: M L KAVANAGH GRO-C DATE SIGNED: 10 May 1990	COUNTER SIGNATURE: REGIONAL PMI SMI / HMI GRO-C 15/5/90

The factual matter contained in this report relates only to those [illegible] actor(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.

FSH.

CONTENTS

Oxford Regional Blood Transfusion Centre
John Radcliffe Hospital
Headington
Oxford
OX3 7LJ

Telephone: 0865 65711

1. INTRODUCTION

Oxford RTC, opened in 1979, is connected to the John Radcliffe Hospital. Although the Centre has its own self-contained area on a single floor, there are security problems arising from access to the main hospital on one side and to the engineering/plant rooms on the other.

The RTC serves a population of 2.69 million, collected around 114,000 donations in 1989 and employs 202 staff. The Centre was last inspected in March 1987.

2. SCOPE

The inspection covered the manufacture and control of the products listed in Section 5. Clinical matters, e.g. tissue typing and testing related to patients, were not included.

3. SENIOR STAFF LIST

Dr C Entwistle	:	Medical Director
Dr M Fisher	:	Scientific Services Manager/Deputy Director
Dr D Collins	:	Quality Manager
Mr P Booker	:	Donor Services Manager
Mr J Eddy	:	Administrator
Miss V Austin	:	Donor Organiser
Mrs G Weeks	:	Blood Collection Manager
Mr A Hunt	:	Laboratory Manager
Mr P Bowell	:	Laboratory Manager
Mr M Woodward	:	Head, Standard Reagents Laboratory
Mr J Strange	:	Head, Donor Grouping Laboratory
Mr A Puckett	:	Head, Microbiology Laboratory
Miss J Kenworthy	:	Head, Blood Products Laboratory

4. CHANGES SINCE LAST INSPECTION

Following a study of the Centre by the RHA Management Services Department, a major re-organization of the RTC management structure has been undertaken. The laboratory organization and the donor services organization have been completed (see Section 3). The appointment of a Business Services Manager, also recommended following the RHA study, has not yet taken place.

The computerised control system has been extended and now all products, including BPL products, are issued via the computer. Donor records are also computerised.

The Microbiology laboratory is now equipped with a Hamilton Micro LabAt automated liquid handling system, giving positive sample identification.

5. LIST OF MEDICINAL PRODUCTS

Product	Units Issued (1989)
Whole blood	17,388
Plasma-reduced red cells	13,915
SAG-M red cells	64,611
Filtered red cells	62
Platelet concentrates (conventional)	15,767
Platelet concentrates (apheresis)	1,215
Cryoprecipitate	50
Fresh frozen plasma (FFP) for clinical use (adult)	6,536
FFP for clinical use (paediatric)	1,042
FFP for fractionation at BPL, recovered (Kg)	24,434
FFP for fractionation at BPL, apheresis (Kg)	1,380
Hyperimmune plasma for fractionation at BPL (Kg)	528

The above figures include the following issues to NE Thames and other RTCs:

Whole blood	155
Plasma-reduced red cells	715
SAG-M red cells	11,310

6. INSPECTION

6.1 Blood Collection and Receipt

Standard blood donations are collected at mobile donor sessions throughout the Region, all teams being based at the Centre. There is also a donor apheresis clinic in the RTC. During the inspection, visits were made both to the Donor Clinic and to a Mobile Session (in Chipping Norton Town Hall).

6.1.1 Donor Apheresis Clinic

The Donor Clinic is equipped with 6 x Haemonetics PCS machines and 2 x Haemonetics V50s. (At the time of inspection, a Baxter Autopheresis C was on trial but was due to be returned within a week). There are approximately 560 donors on the panel, about 105 being bled per week. There are plans to increase these numbers so that platelet concentrates will be predominantly produced by apheresis.

Donor records are now computerised and have been since 1988. The records for the following week's donors are printed out each week and held in the Clinic. When a donor attends and has signed the consent form, the Session Sheet is manually filled in with the name, donation number and group (from previous history). A set of 7 bar-code labels is issued. 1 label is stuck on the top of the donor record sheet and 1 on the lower portion. 2 sample tubes (1 for grouping, 1 for microbiology) are also given bar-code labels. Additional samples are for routine haemoglobin assay (every donation) and liver function/cholesterol testing (once per month) and these are given pre-printed labels carrying the donor's name, donor number and date of birth.

A donor attendant takes the donor, together with the record sheet, sample tubes and labels to a bed by a pre-prepared machine. The batch numbers of the harness and coagulant are recorded in log-books kept by each pheresis machine. However, the batch number of lignocaine hydrochloride, which is used routinely, is not recorded.

At the end of the donation, the pack (and associated equipment) is wheeled on a trolley into a side (preparation) room where it is heat-sealed. If FFP for paediatric use is being prepared, 9 x 50 ml packs are connected to the main pack using a Haemonetics sterile docking device. There is no SOP for this operation and no microbiological validation of the procedure has been performed. A number of unsigned, undated, handwritten instructions and reminders are attached to the walls; these were said to be for helping new staff members.

The bar-coded labels issued at the clerking table are only sufficient to label 5 of the 9 paediatric plasma packs so the remaining 4 are given luggage labels with the donation number hand-written on. Bar-code labels are subsequently generated in the Grouping Laboratory using a bar-code printer.

At the end of the day, the computerised records are updated by keying in the first and last numbers and the total number of donors (to identify the session). All individual donations are also wanded in. Access to the computer is restricted, so any missing numbers have to be adjusted for by computer staff.

6.1.2 Mobile Session

Donors at mobile sessions are mainly "called", the pre-printed computer-generated record sheets being taken to the session. Typically, around 200 donors would be called to a session, with an attendance rate of about 50%. For new donors and "walk-ins", yellow record sheets are used, the appropriate information being hand-written in.

Haemoglobin testing is carried out using the copper sulphate method with blood taken from a finger prick. The limits of acceptance are 125g/litre for females and 135g/litre for males. The copper sulphate is not subject to any QC testing (e.g. specific gravity measurement) prior to use and the criteria for changing to fresh solutions are very haphazard. If a donor fails the test, then it is repeated; if this also fails, a sequestrine sample is taken for subsequent examination and the donor is not bled.

For accepted donors, when the consent form has been completed, a set of 7 bar-code labels is issued and the Session Sheet (white for known donors, pink for new donors) is filled in with the donor's name, donation number and any other relevant information. The donation number is written onto the donor's record sheet at this point, the bar-code labels only being attached when a donation has actually been given. The bar-code numbers are then attached to the record sheet with a paper clip and given to the donor. This policy of only loosely attaching the labels to the sheet and giving them to the donor can produce situations where records and labels can become separated and mixed.

The Team Leader guides donors to the bleed beds, checking the identity of the donor on the way. However, the identity check does not involve the donor giving any information, such as name, address and date of birth, but merely to answer yes (or no) to the information proffered. Subsequent checks by the donor attendant (DA) and MO follow the same pattern.

The DA prepares the donor, wiping the arm with MediPrep wipes, and then a "sterile girl" (a designated DA in a surgical gown) swabs the arm with chlorhexidine and covers it with lint while awaiting venepuncture. Venepunctures are performed by the MO and lignocaine is used routinely but the batch number is not recorded. At the session visited, the policy was for the MO to draw up to 20 syringes of lignocaine at a time and carry them in his pocket.

Once the donation is under way, the DA applies the bar-code labels. 1 is stuck on the top of the record sheet, 1 on the lower portion and the remainder on the packs and sample tubes. It was said that, if a labelled sample tube was broken before it was used, a substitute tube would be given a hand-written label. Generally, the rule is one DA per donor but during busy periods it is not uncommon for one DA to deal with two donors simultaneously, a single table between two beds carrying two sets of sample tubes and labels. Spring balances used to monitor donation volumes are not subject to regular checking with standard weights.

At the end of the donation, the bleed line is clipped off and taken to the "sampler's table", where the pack is stripped and the line hand-sealed near the pack. Samples are racked and the blood is put into crates. The crates of blood remain in the session venue until the session is completed (up to 4 hours) with no attempt being made to monitor or control the temperature of storage.

Blood is transported back to the Centre in vehicles which supposedly have a refrigerated compartment; however, there is no system of monitoring the temperature and, as the refrigeration system depends on mains electricity, it is often not used. The van being used at the session visited did not have its refrigeration system functioning. Some journeys from distant sessions can take up to 4 hours.

6.2 Blood Products Laboratory

The Blood Products processing area comprises a centrifuge room, and a closed-system processing laboratory with a clean-room and changing room leading off it. Since the last inspection, the clean-room has been reduced in size to give more space in the main processing laboratory.

When blood is delivered from a session, each pack is wanded into the computer (by session and pack type) before being transferred to the centrifuge room. This is equipped with 14 x Beckman J6-B centrifuges and 1 x IEC Damon machine, which is on loan. Centrifuges are said to be cleaned regularly but cleaning records are not kept. Cleaning of rooms is by outside contractors (MediClean) and a new contract was being negotiated at the time of inspection. Some dust was noted on a shelf behind the centrifuges.

The main processing laboratory is next to the centrifuge room at the end of a corridor. The door (from the corridor) is permanently wedged open and in warm weather the windows to the outside are open, allowing the ingress of dust, debris and insects. A number of plasma expressors stored on an over-bench shelf were covered with a layer of dust. There are no written and logged cleaning procedures for the area or equipment. Paint is flaking off the walls.

The laboratory in general is very cluttered. Apheresis (Haemonetics) platelet preparations are left to disaggregate on the dirty top of a cupboard in the middle of the room. The temperature of an incubator used for holding pre-issue platelets is monitored by a circular chart recorder supposedly checked daily and changed weekly. The chart in use at the time of inspection had not been changed for six weeks.

If a pack bursts during processing, it is discarded. The procedure in such instances is to enter "discard" into the computer against the donation number and also to record the details manually in a book. If the computer is down for any reason when this happens, the book is the primary record and details from it are supposedly entered into the computer retrospectively. As a meaningful record, the book is completely useless, containing an untidy jumble of altered numbers, ticks and crossed ticks and lacking signatures and details of any action taken There were discrepancies between the book and the information held on the computer.

The procedure for removing microbiology positive products from the Blood Products laboratory is inadequate. Two different types of form notifying Blood Products of the packs to be removed are in use. If the department is un-manned when the form is brought down from Microbiology, it is left on a desk already cluttered with papers and documents. The record maintained in Blood Products of positive material removed consists of a book listing the products concerned; if a product is sent to Microbiology, it is crossed out. There are no dates entered, no signatures of the person responsible and no receipts provided by Microbiology. (See also Section 6.4.)

Open processing is now no longer performed other than the occasional washing of red cells for boosting anti-D donors (performed by Dr Fisher). Although the clean room is supposedly at positive pressure relative to the changing room, the flap-valves were not open; there is no pressure gauge monitoring the pressure differential.

6.3 Donor Grouping Laboratory

The Donor Grouping Laboratory is equipped with a single Kontron Groupamatic 360-C which has been in service since 1979. Since the last inspection, a Technicon Auto Grouper 16-C had been brought as a back-up machine but it only handled samples at around one third of the rate of the Kontron's 330 per hour and also gave other problems; consequently, it has been withdrawn from service.

The anticoagulated samples from known donors are spun down overnight by an Orderly and put on a trolley for collection by Grouping staff in the morning. All samples for new donors go to Microbiology; those found microbiology negative are released to Grouping the following day, together with a computer-generated list of the samples and a summary of the results.

Reagents for use in the Groupamatic are made up in-house. The bottles are labelled with the "recipe" for each reagent and the records of reagent make-up consists of a high-lighter pen line drawn through each ingredient. There are no separate records of weighings, dates or signatures. For second runs through the machine, cells from the previous day's samples are used as reagents. There is no SOP for making up the cells and no records at all are kept.

Each day, known positive and negative samples are run through the machine before the donor samples are loaded on. If the Groupamatic is unable to read the bar-code number of a sample, then the sample is manually grouped. If the machine is unable to interpret the results, the sample is run through again; if it again fails to give a group, it is put through a third time. After a third failure, the results are interpreted manually.

All new donors are grouped twice and at least one of these must be a machine grouping. If a new donor cannot be machine-grouped then the sample is manually grouped (once), the computer entry is "results all manual" and the donation goes to plasma only; the computer prevents the labelling of the red cells. All samples which cannot be machine-grouped are manually grouped.

The Groupamatic is not directly linked to the main-frame computer holding the donor records but it records the grouping results onto hard copy and onto cassette tape. The cassette is used to transfer data from the Groupamatic to the mainframe via a second terminal in the laboratory. At this point, the computer automatically compares the grouping results with the groups held on the donor records. The manual grouping results are in-put via a keyboard and verified by a second person re-entering them. Computer access is restricted by individual passwords (operators' initials followed by individual 3 digit codes). There is no policy for changing passwords on a regular basis.

A set of SOPs (authorised and released the previous day) was available in the laboratory. Several of these lack essential detail. There were a number of unsigned, undated, handwritten procedures posted around the walls of the laboratory.

In a fridge in the Grouping Laboratory, there was a pack of SAG-M red cells with a preparation date of 22 February 1990 (i.e. 5 weeks previously) and a group label (O Rh positive) attached to it by means of an elastic band. No immediate explanation was available as to its history. (See Section 6.4.)

6.4 Microbiology

All samples are tested here for HBsAg, HIV antibody (both Wellcozyme ELISA) and TPHA (modified Fujirebio). In addition, selected samples are screened for antibodies to CMV (Becton Dickenson). Within two weeks of the inspection, it is planned to start testing for antibodies to HIV 1+2 (Wellcome).

The laboratory is equipped with a Hamilton Micro LabAt automated sample handler. Sample tubes are racked and entered, via a light pen, into the computer, to identify each tube's position. The rack identification number is keyed in and the Hamilton sub-samples into bar-coded Microtitre plates, giving positive sample identification.

Reagents are added manually in the general laboratory and then the plates are passed through to the containment area, which is at negative pressure relative to the surrounding areas (indicated by flap valves). Controls are added by pipette in a microbiological safety cabinet within the containment laboratory. Kit controls are used on every plate for HBsAg, HIV antibody and TPHA. In addition, the CPHL (Colindale) low positive and very low positive controls are included for HIV antibody testing. The Colindale QC sample panel is tested monthly.

For the plate-readers (in the containment laboratory), the disk with the information from the Hamilton is brought in and transferred to the IBM computer, the plate bar-code being wanded-in. If a sample gives a positive or equivocal result, the test is repeated on the same sample. There is no defined procedure for confirming that the correct sample has been removed from the rack for repeat-testing. If the repeat test is positive then, in the case of HBsAg, a neutralisation assay is performed.

The procedure for dealing with donations which test microbiologically positive is inadequate. Initially, Microbiology staff check the computer listing to obtain details of the products made from the affected donation, at the same time entering on the computer "microbiologically positive" against the donation. This action should prevent the issue of any products.

A form listing the products affected is filled out and taken to Blood Products but if that department is un-manned, the form is left on a cluttered desk. (See Section 6.2). If platelets have been made from the donation, the procedure apparently is for Microbiology to remove them and leave a note informing Blood Products of their action. Red cell products are also supposedly removed by Microbiology staff; plasma, however, is the responsibility of Blood Products staff, who remove it when convenient and pass it to Microbiology.

The records kept in Microbiology of the withdrawal and disposal of positive products are totally inadequate. There is no list of the products made, just the donation number. There is no record of the final fate of the packs concerned, e.g. autoclaving or held in the laboratory. The records, such as they are, are incompletely maintained. There is no procedure for follow-up if packs are not delivered to Microbiology. There is no signed "receipt" given to Blood Products staff when packs are delivered to Microbiology.

The flaws in the procedure were highlighted with the case of the SAG-M red cell pack in the Grouping Laboratory fridge (see Section 6.3). It transpired that the donation had been identified as TPHA positive but instead of withdrawal and disposal, it had been put into Grouping fridge. In order that a Group label could be issued for it, the donation was entered as "clear" on the computer record. However, although the red cells were held (albeit in the wrong fridge and the wrong laboratory), the effect of altering the computer entry was to enable the plasma to be cleared for issue. Investigations during the inspection revealed that the plasma had, in fact, been despatched to Elstree some 3 weeks previously. (Steps were taken at the time of inspection to have the pack recalled from Elstree.)

Confirmatory tests for samples found repeat-positive are carried out at the CPHL, Colindale, and PHLS at the John Radcliffe Hospital. The keeping of library sera samples has very recently been instigated (26/3/90) and they are being kept on Microtitre plates.

6.5 Blood Bank and Issue

Cleared blood is kept in a cold room separate from the cold-room for quarantined blood. The room is kept in clean and tidy condition. The cold rooms are monitored by a chart recorder and are also fitted with an alarm system. At the time of inspection, the alarm system was giving trouble. The "cancel" button did not always re-set itself and the back-up "reminder" alarm was broken. Repairs were awaited.

FFP and cryoprecipitate are stored in a chest freezer in the corridor, the temperature being monitored on a chart recorder and by alarm. Platelet incubators (22±2°C) are also kept in the corridor and have local alarms. The temperature is indicated digitally but they have not been calibrated.

Orders for blood and products are received by telephone and a triplicate Request Form is completed. Orders are put together and wanded through the computer, which alters the stock list accordingly and prints out a delivery sheet. If the computer is down (a fairly common occurrence, which happened during the inspection), a manual record is kept in a book for retrospective entry into the computer. Occasionally, wrong numbers are entered into the manual record.

All records are now held on computer, including BPL products. A physical stock-check is performed every week. All returns of blood and red cell products are discarded (and entered as "Disc" on the computer.

A "working stock" of Human Albumin Solution is held on the floor of the despatch area under a bench. Some of this material had obviously been there for some time and was covered with dust and dirt.

6.6 Quality Control

The work of the Quality Control department currently consists of a very limited amount of quality monitoring and an equally limited amount of environmental monitoring. Dr D Collins was appointed Quality Manager in mid-1989.

The QC laboratory is equipped with a Technicon H1 Junior cell counter and this is used to check the quality of platelet concentrates. Preparations are selected randomly, 10 from the day shift, 6 from the evening shift and 4 Haemonetics preparations if they are available. Packs are sampled non-invasively and checked for platelet count, white cell count, red cell count and weight. Specifications (known here as targets) are those of the NIBSC/UKNBTS Guidelines, viz. volume 50-60 ml, platelet count >55 x 10^9/unit, white cells <0-12 x 10^9/unit and red cells <1.2 x 10^9/unit. On average, around 60% the platelet preparations fall out of specification. No action is being taken to improve this situation. There is no monitoring of pH at the end of the shelf-life.

The only other quality monitoring of products is the weighing of SAG-M red cells and plasma by the production staff. 10 paired units of plasma and cells are weighed each weekday and the total weight of the original donation is derived by addition. No coagulation assays are performed at the Centre, although there are long-term plans to buy a coagulometer.

The results of the quality monitoring are summarised in a weekly report which is circulated to Dr Fisher, Dr Collins, Mr Bowell and Mr Hunt. Monthly meetings are held with QC production staff and a twice-yearly report is published and circulated.

Some environmental monitoring and microbiological testing is performed by the Microbiology department. Arm swabs are taken from donors pre- and post-cleansing once a week and are plated out on plates brought in from the hospital. The plates are not sterility or fertility tested at the Centre and batch numbers are not recorded. Plates are incubated at 30°C for approximately 48 hours but records of the incubations are not kept. The results are circulated to interested parties, including the Donor Manager.

Up to 20 packs per week of out-dated platelets are cultured and occasionally excess red cell preparations are also tested. The SOP available was out of date and gave incorrect incubation times, temperatures and methods. Three types of broth are used, Brain/Heart, Thioglycollate and Glucose. Records are inadequate and do not list incubation on and off times nor the dates of reading. The incubator temperature is supposedly monitored by a thermometer but at the time of inspection it could not be found.

Environmental monitoring consists of swabbing selected areas and plating out on blood agar. Areas covered are Blood Issue, Blood Products (including the clean room) and the Labelling Area. There are no action/alert limits.

There is no overall Quality Assurance programme with centralised responsibility for such matters as SOP production and co-ordination, temperature monitoring, review of autoclave records and clean room/LAF cabinet data. There is no system of self-auditing.

7. FUTURE PLANNED CHANGES/DEVELOPMENTS

Long-term plans include increasing the use of the Donor Apheresis Clinic such that all platelet concentrates are produced by apheresis machines. (At present 95% of platelet concentrates are from ordinary sessions).

There are plans to equip the QC laboratory with coagulometer and to increase the quality monitoring programme.

8. MATTERS OF CONCERN

a) At donor sessions and in the Donor Clinic, the batch number of the lignocaine used is not recorded.

b) For donor identification checks, donors are not required to give their names and addresses, merely having to agree to information offered them.

c) At donor sessions, sets of bar-code labels are loosely attached to donor record sheets (with a paper clip) and are given to the donors.

d) Balances used at donor sessions are not regularly checked with standard weights.

e) Conditions and procedures in the Blood Products Laboratory are inadequate. In particular:

i) There are no written, logged cleaning procedures. Plasma expressors were covered with a layer of dust.

ii) Windows to the outside are frequently opened, allowing the ingress of debris and insects.

iii) Platelet packs are left lying on the top of a dirty cupboard in the middle of the laboratory.

iv) The 7-day temperature recording chart on the platelet incubator had not been changed for 6 weeks.

v) The manual record of the fate of burst packs is in need of complete revision. The existing record contains a mixture of altered numbers, ticks and crossed ticks, carries no signatures and does not agree with the computer record.

f) The records for reagent make-up in Donor Grouping consist of a line drawn through the ingredients on the label; no operators' signatures or dates are recorded.

g) In Donor Grouping, there are a number of unsigned, undated, handwritten procedural notices on the walls. There is no SOP for the preparation of cells as reagents.

h) The procedure for dealing with microbiology positive donations is inadequate. In particular:

i) There is a split of responsibilities in the procedure for quarantining microbiology products.

ii) If the Blood Products laboratory is unmanned, the form listing the positive products is left on a cluttered desk.

iii) There is no procedure for following-up positive packs which are not promptly delivered to Microbiology.

iv) The records in Microbiology of the fate of microbiology positive donations are totally inadequate; the associated products are not listed and the date and final disposition of the packs are not recorded.

i) A plasma pack from a donation identified as TPHA positive had been sent to Elstree because of a breakdown in procedure.

j) Boxes of Human Serum Albumin, stored on the floor under a bench in the Issues area, were covered in dust and dirt.

k) The Quality Control department is under-equipped and under-staffed permitting only minimal quality and environmental monitoring.

9. POST-INSPECTION SUMMARY

After the inspection, a discussion took place with the Medical Director, the Deputy Director and the Laboratory Managers. The Inspector acknowledged the extent of the reorganization that had taken place and welcomed the improvements that had occurred since the last inspection, particularly the extension of the computerised system to incorporate the logging-in of each donation, the issue of plasma to Elstree and the issue of Elstree products. However, the Inspector also expressed concern at the lax procedures in place for dealing with microbiology-positive donations, as evidenced by the despatch of a pack of plasma to Elstree from a donation identified as TPHA positive.

The deficiencies noted above (Section 8) were listed and discussed.

10. CONCLUSIONS

1. There should be an immediate review of procedures for dealing with products from donations identified as microbiology positive.

2. The Quality Control department should be expanded to enable the introduction of a full programme of Quality Assurance, with particular attention being given to record keeping.

3. Current procedures and practices are not of a standard which would be expected to meet any future licensing requirement.