NOTE OF MEETING HELD AT THE BLOOD PRODUCTS LABORATORY, LISTER INSTITUTE

ELSTREE, HERTS. ON TUESDAY 27TH MARCH 1973

Present:	Dr. I.S. Macdonald	Mr. L. Vallet
	Dr. R.A. Cumming	Dr. D. Ellis
	Mr. J.G. Watt	Mr. E.D. Wesley

Building Progress

Mr. Vallet reported that the new building at Elstree was formally taken over in February, 1972 with many items in the services and process equipment incomplete. In the second half of the year, fractionation of plasma in the new laboratory began and in the last quarter a total of 10,300 litres of plasma was processed and 39Kg of immunoglobulin (bulk), 171 Kg PPF concentrate and 46 Kg Albumin concentrate were produced. The weights refer to protein. The plant is now taking plasma at its planned capacity of 1500 litres weekly. In addition to the large scale work on normal plasma, the small fractionation unit is taking pools of special plasma for specific immunoglobulins. There has been considerable delay in delivery of equipment for preparation of final solutions. The hot-air cabinets for heat treatment of albumin solutions have only recently come into routine use so production of bottled PPF from concentrate is still being worked up to the planned level of 2400 bottles per week. The automatic filling and packing equipment for immunoglobulin was expected to be in use in the summer. The final total cost of £870,000 for the new building took account of cost increases but there had been no major change in the scale of capital equipment. Modifications to the old building under a separate contract were still in progress. Renovated laboratories for the preparation of coagulation factors were being taken over from the contractors that week.

Mr. Watt reported that the progress in the construction of the new laboratory at Liberton had been maintained apart from 4 weeks lost in strike action in the building industry, and he expected to begin main commissioning in April 1974. About £400,000 of the total cost of just over £1 million had been spent. In the existing building work on the flow system had continued and this was now being linked to the computer. The holding period for separation had been greatly reduced by the introduction of an aggregation stage between the addition of ethanol and centrifugation.

Fractionation of plasma in the existing plant had been raised to a peak of 500 litres a week to prepare PPF. This has required the storage or discarding of Fraction II + III.

P.P.F.

There was concern about the ultimate level of use of PPF. One estimate for Scotland, which was supported by experience in some other countries, indicated an annual requirement of 10 to 12 bottles per 1,000 population which could rise to 12 to 15 per 1,000. If this level of use became general the facilities for fractionation in the United Kingdom, existing and under construction would be inadequate.

Problems of testing PPF for sterility were discussed including a proposal by Mr. Watt that bottles should be incubated 14 days and examined before heating 10 hours at 60°C and not after heating so that a contaminating organism could not become a potential "slow grower" as a result of partial inactivation by heat. The need for holding PPF for a period at ambient temperature after incubation at 30 to 32° would make great demands on storage space as the scale of preparation increased. At. B.P.L. the procedure of heating 10 hours at 60°C then incubating 14 days at 30 - 32° and holding 3 months at ambient temperature had been followed for over six years. From all the batches examined in this period, a few random bottles with signs of growth had been picked out in the final inspections. It was to be expected that improved conditions in the new laboratory would reduce the incidence of "rogue" bottles where contamination had entered during filling but there was also a potential risk of contamination due to defective seals and containers. Of the bottles filled in the new laboratory only about 2,500 had completed 3 months storage. None had been rejected for signs of growth but it was felt that more experience of large batches was needed before conclusions could be drawn about the value of inspection after 3 months. It was considered undesirable that the two laboratories might evolve different standards of testing (particularly for contamination) through their interpretation and extension of statutory requirements.

It was agreed that although the requirements in the monograph on PPF (Human Albumin Solution) in the new volume of the E.P. would include lower limits for protein concentration and purity of albumin by electropheric analysis, the present limits for protein concentration and purity, 4.3g/100ml, 90% albumin, should be maintained.

Factor VIII and Factor IX.

Time did not permit full discussion of problems concerning these factors. The B.P.L. was at present engaged in reoccupation of the renovated area in the old building allocated for their preparation and plans for a further scale up were being prepared. Mr. Watt stated that the provision of fractionation capacity for plasma from England at Liberton would be for time-expired plasma only. Capacity would not be available for the preparation of coagulation factors from fresh plasma.*

A tour of the new wing of the B.P.L. occupied the afternoon.

* NOTE It has been agreed in principle at a recent meeting at DHSS that fractionation of fresh blood for coagulation factors would be considered for U.K. as a whole.