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STC(81)18

IN CONFIDENCE

THE NATIONAL BLOOD TRANSFUSION SERVICE

THE SCIENTIFIC AND TECHNICAL COMMITTEE FOR THE CENTRAL BLOOD LABORATORIES

Minutes of the 11th meeting of the Committee held on Tuesday 24 November 1981 at the Department of Health and Social Security, Hannibal House, Elephant and Castle.

PRESENT:

Professor P L Mollison - Chairman
Mr R D Smart
Dr B A Wills
Dr H H Gunson
Dr P Dunnill
Dr J Prydie

Directors:

Dr A M Holburn
Dr R S Lane

Joint Secretaries:

Mr S Godfrey
Dr D Walford

In attendance:

Dr J Smith (BPL) - Item 1 only
Mr S Green

RESEARCH PROJECTS AT THE CENTRAL BLOOD LABORATORIES

1. Dr Smith (BPL) gave a short address on the inactivation of hepatitis in BPL products. (A summary is attached at Annex A).

APOLOGIES FOR ABSENCE

2. Apologies had been received from Professor Peters, Professor Flute and Mr Harley.

MINUTES OF THE PREVIOUS MEETING - STC(81)13

3. These were agreed.

MATTERS ARISING

4. a. PROGRESS WITH STAFF APPOINTMENTS AT BPL

THE PART COVERED DOES NOT RELATE TO THE MATTERS IN QUESTION IN THIS ACTION.

b. SHIFT WORK EXPERIMENT AT PFC, LIBERTON

Dr Lane reported that Mr Wesley, head of Large Fractions, and a colleague from BPL had attended PFC's shift-work experiment. He hoped to present Mr Wesley's report to the next meeting of the Policy Steering Group. Dr Lane expressed several reservations about the experiment. He was particularly concerned that certain information provided to the BPL representatives by PFC departmental heads did not seem to correspond with that supplied by the teams involved in the exercise itself; that the plasma used during the experimental period was the remnants of time-expired plasma supplied by BPL some time ago; and that the data from the experiment would not reflect the pressure under which the Laboratory was working. He doubted whether it would give an accurate indication of PFC's potential capacity. Dr Dunnill felt that certain benefits would

be derived from the exercise for example an indication as to whether PFC could handle more plasma. It could also point to the advantages, or disadvantages, of a continuous operation system.

NBTS SYMBOL

THE PARTS COVERED DO NOT RELATE TO THE MATTERS IN QUESTION IN THE ACTION.

BGRL's MOVE TO OXFORD

POLICY STEERING GROUP ON THE REDEVELOPMENT OF BPL

7. Mr Smart reported that the Group had agreed to meet as and when necessary and had done so three times to date. Its work was hampered to an extent by the lack of a Ministerial decision on long-term management arrangements but, working within the terms of reference agreed by the JMC, the PSG had made decisions on the following matters:

i. PFC Liberton

The Group was anxious to encourage greater collaboration between BPL and PFC. In addition to the 2 members of BPL's staff, it had been arranged that Mr Hibbert should visit Liberton as an observor during the shift working experiment.

ii. Time-scale for redevelopment of BPL

A 3-year target had been set for completion of the redevelopment. The Group had noted that Capricode requirements must be met.

iii. Technology

The Group had agreed that cold ethanol precipitation process should be used; and that a modular construction should be adopted, with 2 separate production lines, to facilitate production and varying levels of capacity. The design would need to be sufficiently flexible to be adapted to advances in technology.

iv. Feasibility Study

The Steering Group had commissioned Matthew Hall, Norcain to complete a feasibility study by 10 December 1981.

v. Project Management

Mr Gordon Collins of NW Thames RHA had been appointed project manager.

vi. Involvement of staff

The Group recognised the importance of involving BPL's staff and a meeting between PSG and staff representatives would be arranged to discuss the development.

vii. Alternative accommodation for BPL

Lord Elton, Parliamentary Under Secretary had suggested to Dr Harris that the Group should consider the adaptation of an existing factory. The Group had considered this option but, after consulting ABTI, had found no suitable premises available.

PFL OXFORD

8. a. MEDICINES INSPECTORS' REPORT - STC(81)14: DR LANE'S RESPONSE - STC(81)15

Dr Lane explained that he had provided the Medicines Inspectorate with STC(81)12 which outlined the proposed transfer of the bulk of PFL's production work to BPL. However, some production work would continue at Oxford and the report had been critical of certain aspects of PFL's production facilities. It did however reflect a high opinion of PFL's staff. The response (STC(81)15) detailed the steps taken to correct the shortcomings highlighted in the Inspectorate's report. Considerable progress had been made and Dr Lane had included a sum for air-conditioning within the Laboratory's capital bid for 1982/83. On site discussions had been arranged with the Inspectorate. The Committee noted Dr Lane's paper.

b. REORGANISATION OF PFL - STC(81)12

The Committee emphasised that sufficient priority should be given to PFL during BPL's redevelopment period because of its important role in product development and small-scale manufacture of certain products.

RESEARCH AND DEVELOPMENT AT BPL - STC(81)16

9. The Committee discussed in detail each of the research proposals set out in Dr Lane's paper and considered the possibility of DHSS or MRC/Industry funding. Given the importance of, and potential savings to be derived from, increased product yield, the Committee felt that projects 3 and 6 would be appropriate for DHSS funding and suggested that Dr Lane should prepare a protocol, which the Committee would endorse, for

consideration by the Office of the Chief Scientist. Dr Lane agreed to pursue other possible sources of funding for the remaining projects.

SUPPLY OF FIBRINOGEN TO AMERSHAM

10. Dr Lane explained that to meet the Radiochemical Centre demands for fibrinogen required the establishment and maintenance of an accredited donor panel which involved additional work and expenditure by NW Thames RTC. There were some benefits for the NHS in terms of products derived from the plasma concerned. Given the difficulty in collecting suitable plasma, it was agreed that since an alternative source of supply was available to Amersham, the provision of fibrinogen for isotopic labelling should not be regarded as a priority by BPL.

ANY OTHER BUSINESS

11. a. BPL/PFC PRODUCT SPECIFICATIONS

Mr Smart reported that the PSG had asked the Department to provide product specifications for BPL and PFC. The Chairman asked for the specifications to be circulated to STC Members, together with product labels, and invited Members to comment on both in writing as soon as possible.

b. MEDICINES INSPECTORATE'S REPORT ON BPL, MARCH 1981

Dr Lane stated that the Medicines Inspectorate had asked for further details of remedial work undertaken following their report in March 1981. Dr Lane had therefore prepared a supplementary report /now designated STC(81)17/ covering those points on which the Inspectorate had sought additional comments. He hoped to discuss this with Mr Haythornthwaite on his next visit. Mr Godfrey said that the report, together with a note of the STC's endorsement, would be passed on to Medicines Division.

DATE OF NEXT MEETING

This will take place on Tuesday 16 February 1982 at 2.00pm in room 65, Hannibal House, Elephant and Castle.

ANNEX A

INACTIVATION OF HEPATITIS IN BLOOD PRODUCTS LABORATORY PRODUCTS

The review covered the consequences of transmitting both B and non-A non-B hepatitis viruses, the incidence of infection among multi-transfused haemophiliacs and the special problem of infrequently transfused patients who had no immunological defence. The risk of transmitting hepatitis might be diminished by more specific and sensitive screening of blood donations intended for fractionation; limiting the size of plasma pools for recovery of certain products; neutralization or adsorption of virus with an excess of hepatitis antibody; vaccination of recipients; selective removal of viruses during fractionation, eg by precipitation with PEG; and by inactivation of virus eg with B-propiolactone or by heating in the presence of reagents preserving the biological activities of plasma proteins. A policy was suggested for the selective application of these approaches to individual coagulation factor concentrates.

DR J SMITH
BPL