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IN CONFIDENCE

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NATIONAL BLOOD TRANSFUSION SERVICE - SCIENTIFIC AND TECHNICAL COMMITTEE FOR THE CENTRAL BLOOD LABORATORIES

The minutes of the 4th meeting of the Committee, held at 2.15 pm on Wednesday, 23 January 1980.

PRESENT	Professor P L Mollison (Chairman)	DIRECTORS
	Dr P Dunnill	Dr A M Holburn
	Professor P T Flute	Dr R S Lane
	Dr H H Gunson	JOINT SECRETARIES
	Professor D K Peters	Mr T E Dutton
	Dr J Prydie	Dr Diana Walford
	Mr R D Smart	IN ATTENDANCE
	Dr G H Tovey	Mr J Harley
		Mrs S C Yuille

Apologies were received from Dr Wills and Dr Glass.

MINUTES OF THE PREVIOUS MEETING-STC MINUTES 79/3

The minutes were agreed and signed as a correct record.

MATTERS ARISING FROM THE PREVIOUS MEETING

Progress with the relocation of the Blood Group Reference Laboratory

The Secretary reported that at a meeting held in Oxford on the previous day, the Area Health Authority had formally agreed to make the Harkness building available for use by the Blood Group Reference Laboratory. There remained the question of finding an alternative location for the University workshops on the ground floor of the building, but it was not anticipated that this would give rise to insuperable problems. The Committee urged the Department to ensure that the move was completed within 12 months if possible.

THE FUTURE OF THE BLOOD PRODUCTS LABORATORY, ELSTREE (STC(80)1)

Mr Smart enquired whether BPL's complying with the recommendations of the Medicines Division was voluntary or mandatory. Dr Walford explained that whilst there was Crown exemption, successive Secretaries of State had stated the intention that NHS establishments should conform to the standards required of industry. Mr Smart asked how the Department could reconcile this statement with the decision that the Blood Products Laboratory should continue to function without upgrading it to the full extent required by Medicines Division. He thought that the position which the Department appeared to be taking up was not an attractive one and Dr Dunnill remarked that it was not one which was in any way technically acceptable. The Committee agreed that, as presented to them, they could not endorse the views attributed to Ministers. The Secretaries explained that since the paper had been prepared there had been further discussions on the upgrading required at the Blood Products Laboratory and that Mr Harley would be able to confirm that there was to be a substantial measure of upgrading. Dr Lane acknowledged that although it fell far short of all that required to be done the Department had intimated that they would be in a position to provide money for substantial upgrading at BPL in the coming year. Nevertheless, he felt his position to be a particularly invidious one professionally. He wished to know for how long he would be required to accept the professional risk attendant on directing the present laboratory. Quite apart from the shortcomings to which the Medicines Inspectors had drawn attention, it should be appreciated that most of the plant in the laboratory was now between 10 and 15 years old and was liable to repeated breakdowns.

Mr Harley explained that Ministers had decided to defer the eventual decision on building a new laboratory within the NHS until the other possibilities had been investigated.

There had been several requests from industrial companies to discuss a co-operative venture with the NHS to produce blood products and the first requirement was to open discussion with industry about the kind of service which they could offer. Supply Division would take the lead in these negotiations. Dr Vaughan had asked to be kept in close touch with the situation at the BPL and he was shortly to visit the Laboratory. Dr Lane pointed out the need to ensure that the Minister fully appreciated the inter-dependence between the laboratory and the Regional Transfusion Centres. Dr Dunnill questioned whether, given that blood was voluntarily donated in this country, collaboration with industry was a practical

proposition. Mr Smart thought that if the right questions were put to industry, it would soon become apparent whether or not such collaboration was a practical alternative to rebuilding a Blood Products Laboratory within the NHS. He thought that a suitably worded questionnaire would reveal what the companies had to offer; a questionnaire would be drawn up by Dr Walford in conjunction with Mr Smart and other members of the Committee. After further discussion it was acknowledged that on the basis of what the Committee had been told it was apparent that it was the intention to carry out a substantial amount of upgrading at BPL. Members therefore suggested that the statement of the Department's intentions might be reworded to avoid the difficulty if the Minister's decision were construed as leaving a large gap between what was to be done and what Medicines Division recommended should be done at the Blood Products Laboratory. Mr Smart undertook to circulate suitable rewording for consideration by members. Dr Gunson reminded members that whatever the outcome of the consideration being given to a new BPL, or some industrial alternative, it would be necessary to match any central development with equivalent development in the Regions, otherwise the plasma would not be available. Dr Tovey and Mr Smart agreed to be available to meet the Minister when he visited BPL and to draw his attention to considerations of this kind. Mr Smart expressed the view that there may well be no alternative if the Blood Transfusion Service was to be geared up to meet the requirements of a modern fractionation plant for plasma, to the establishment of a special health authority incorporating the BPL and the NBTS.

PROJECTS NECESSARY TO MEET INTERIM REQUIREMENTS OF THE MEDICINES INSPECTORS

Dr Lane described what he was doing to upgrade the documentation of the laboratory and undertook to have examples of the new documentation available at the next meeting. Proposals were in hand to improve laboratory cleaning and it was intended to provide all the special clothing necessary for staff working in clean and sterile areas. Plans were in hand to introduce stepover facilities at strategic points in the laboratory and complete monitoring of the environment would be introduced as soon as possible. He hoped the Department would now agree to 'stop gap' going ahead and he drew the Committee's attention to the reasons why he felt that it would be inadvisable to drop the provision of fixed cold room space from the 'stop gap' project. He thought that all the cold space available in 'stop gap', and that which he proposed to provide by the purchase of modular cold room facilities, would be necessary, particularly when the stage was reached of reworking the coagulation factor premises. The re-working of the

CF premises, which might eventually cost about £½ million, was absolutely essential if he was to safeguard the output of factor VIII. Dr Lane then outlined his proposals for resiting the microbiology unit which would release space to provide changing rooms, an interview room etc, thereby isolating the main production laboratory which could then be reworked to provide separate sterile and clean areas. The Medicines Inspectors had been particularly critical of the ceilings in the manufacturing laboratory and if the standards which they required were to be adopted, it would be necessary to replace most of the ceilings. It was doubtful whether the air conditioning requirements could be met without a complete rebuilding. Dr Lane sought the Committee's agreement to making changes in the upgrading programme if events demonstrated that these were necessary. The Committee agreed that this might be unavoidable. Dr Lane pointed out that when he had framed his budget to 1980/81 he had not received the definitive statement of the Medicines Division requirements. This had now reached him and he was considering the financial and other implications.

THE BLOOD PRODUCTS LABORATORY HEPATITIS RADIOIMMUNO ASSAY

Dr Lane outlined his proposals for making this assay available to the Health Service at a cost very substantially below that which Centres were currently paying for radioimmuno assay. It was agreed that a switch to RIA was desirable and Dr Lane's tests seemed to provide the answer. After discussing possible ways and means of financing the development of the tests at BPL, for which a further £60,000 would be necessary in 1980/81 and rather more in 1980/82, members recommended that the Department should consider all possible means of funding this project and, if necessary, invite Regions to pay for it.

QUALITY CONTROL OF FACTOR VIII

Dr Lane outlined the circumstances in which 2 batches of factor VIII had been found to contain unwanted materials. When the nature of the material was described to the Committee, they unanimously agreed that the factor VIII in question could safely be issued.

REPORT ON PROGRESS WITH THE PRELIMINARY PLANNING OF THE POSSIBLE PHASED RE-DEVELOPMENT OF BPL

Dr Lane described the outcomeof the meeting that had been held for this purpose at BPL and invited the Committee's comments on the advisability of appointing a project manager. It was agreed that if BPL was to be totally redeveloped a

project manager would certainly be required and the Department was invited to consider whether, in view of the scale of upgrading now envisaged, it might be advisable to appoint a project manager for that purpose. Dr Dunnill asked the Department to consider whether they were satisfied that there was sufficient engineering expertise at the disposal of those who were considering the upgrading and planning of a Blood Products Laboratory. Mr Harley explained that money might be found by the Department to pay for the services of certain specialist advisers and he would make enquiries to establish whether specialist engineering advice for BPL could be obtained in this way. Dr Lane urged that consideration of the phased redevelopment of BPL should continue and not be deferred pending discussion with industry.

The parts covered by [redacted] relate to the matters in question in this action.