

SCOTTISH HEALTH SERVICE

COMMON SERVICES AGENCY

MINUTES OF A MEETING OF THE MEDICINES INSPECTORATE AD HOC PROJECT STEERING GROUP HELD AT 10.00 AM ON THURSDAY 11 NOVEMBER 1982 IN COMMITTEE ROOM 2, TRINITY PARK HOUSE, EDINBURGH.

Present: Mr R Wallace (Convener)
Dr A E Bell
Dr J D Cash
Miss M Corrie
Mr M J Ord
Dr R J Perry
Mr J O Wastle
Mr J G Watt
Mr C H Wooller

22. MINUTES OF PREVIOUS MEETING

The minutes of the meeting held on 16 September 1982 were submitted and approved as a correct record.

23. PROTEIN FRACTIONATION CENTRE - DRAFT REPORT

Consideration was given to a draft report, copies of which had been circulated, summarising the proposals which had been developed by the Group to meet the criticisms of the Protein Fractionation Centre by the Medicines Inspectorate.

During the course of the discussion which ensued it was noted that in recent weeks it had become apparent to senior staff at the Protein Fractionation Centre that the proposals developed for implementation in Phases II(a), III and IV required to be reassessed in the light of further discussion of the implications for the whole process of the installation of a Tunnel Washer/Filler in Phase II. It was also agreed that the report should inter alia:-

- (a) reflect the terms of the remit given to the Group by the Blood Transfusion Service Sub-Committee
- (b) identify the assumptions which the Group had been obliged to make in formulating its proposals ie
 - (i) the professional judgement that the estimated production capacity for Scotland and Northern Ireland for the next decade equates to an input of 80 tonnes of plasma per annum;
 - (ii) total fractionation of the plasma input, the policy and revenue implications of this decision being considered as they arise;
 - (iii) the desirability of opting for the highest technology, fully automated approach;
 - (iv) the consequence for staff in terms of the qualifications of future employees and the redeployment and retraining of existing staff.

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- (c) make a direct response to the criticisms made by the Medicines Inspectorate and clearly identify the deficiencies being remedied by the various proposals.
- (d) indicate the diseconomies of scale where they exist.
- (e) distinguish between medicines inspectorate matters and other desirable developments.
- (f) take account of the fact that the notional cost of the original proposals submitted to the Blood Transfusion Sub-Committee was ~~£4.8M.~~
5.5M.
- (g) identify the consequential staffing proposals.

In the light of the foregoing it was agreed that:-

- (1) the National Medical Director, in consultation with Mr Watt, prepare a revised draft report for consideration by the Group.
- (2) a further meeting of the Group be convened as soon as the revised report became available.
- (3) the Blood Transfusion Service Sub-Committee be advised of the position, in particular of the assumptions the Group had been obliged to consider carefully when formulating its proposals, and requested to note that it might be necessary to convene a special meeting of the Sub-Committee early in the New Year.
- (4) the Scottish Home and Health Department be advised of the position.

24. REGIONAL TRANSFUSION CENTRES - GENERAL RESPONSE

Dr Cash reported that the formal reports had now been received by the Regional Directors and that he had agreed to prepare a general response by the end of November. He further reported that at a meeting held on 19 October involving the Convener and Senior Departmental and Agency staff the undernoted action had been agreed in relation to the major capital building implications of the Medicines Inspectorate reports:-

- (a) Inverness
Existing plans to be informally examined by the Medicines Inspectorate and if accepted, progressed by the local office of the Building Division.
- (b) Aberdeen
 - (i) Brief and notional cost of proposals to be finalised as soon as possible.
 - (ii) Centre staff in consultation with the National Medical Director and Dr Camm, Medical Adviser, Building Division to develop a brief for a new centre as soon as possible.

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(c) Dundee

Further request to be submitted to the Tayside Health Board for the provision of additional space (5,000 sq ft) for the Service, the Board's preferred option ie the building of a new centre being unacceptable because of the operational difficulties, cost and inevitable delay involved.

(d) Edinburgh

(i) Detailed plans to be prepared by the Director in consultation with the local office of the Building Division to redevelop the Blood Bank area.

(ii) Director to review the position of Livingstone House in the light of the anticipated major delay in the Development of Phase II of the Royal Infirmary.

(e) Glasgow

Director to prepare plans for a new blood products production area following the closedown of the plasma freeze drying plant and consider the necessity of providing facilities for the freeze drying of cryoprecipitate.

25. DOCUMENTATION

Mr Watt reported that it had become apparent in recent weeks that the task of creating Standard Operating Procedures was ideally suited to the use of a word processor. Accordingly, in the absence of an agreement within the NHS with NALGO on the use of such technology he had written to Mr Wooller seeking approval to engage the services of an outside agency to commence the task of committing existing documentation to a machine oriented format to assist review and to continue to process further Standard Operating Procedures and manufacturing documents as they became available.