UKBTS/NIBSC

WORKING GROUP ON PLASMA FRACTIONS

Minutes of 4th meeting at NIBSC, South Mimms, Hertfordshire at 10.30am on Tuesday, 8 March 1988.

Present:

Dr D P Thomas	(Chairman)	NIBSC
Dr D R Bangham	(Secretary)	NIBSC
Dr T W Barrowcliffe		NIBSC
Dr B Cuthbertson		PFC, Edinburgh
Dr K T Forman		RTC, Sheffield
Dr J K Smith		PFL, Oxford
Dr T J Snape		BPL Elstree

Apologies from Dr R Thorpe.

Precirculated papers included:

- Agenda
- Minutes of 3rd meeting
- Assignment of Potency to Batches of Factor VIII and Factor VIII concentrates produced by NHS Plasma Fractionation Centres (March)
- 2nd draft (25.01.88) Specification for the validation of virus inactivation procedures used during the manufacture of clotting factor concentrates (B Cuthbertson)
- 1st draft (15.02.88) specification for plasma intended for fractionation (B Cuthbertson)
- 2nd draft Factor VIII concentrates. Product design, intended characteristics (J Smith)

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1 Minutes of 3rd meeting (Jan) were accepted.

Corrections:
- Date of meeting was January 19 not 15
- Dr Forman comes from Sheffield not Leeds
- 2nd line, delete: 'it was'

2 Liaison Group Meeting (2 March 1988) (Reported on by Dr Snape)

- The meeting had coincided with the meeting of the CSM Biological Sub-Committee

- Minutes of the 2nd and 3rd meetings of the WG.PF were considered

- Only sporadic testing of Factor VIII in plasma took place at RTCs

- A trial of ALT testing was being conducted in Scotland

- The WG on Microbiology recommended that UK Working Standardization for HBsAg ad and ay tests should be set up. Until suitable HBsAg standards were calibrated and available it may not be suitable to specify precisely a concentration limit.

- A second Scottish standard for HBsAg is currently being caibrated against the International Standard for HBsAg, which is the ad sub-type. The one standard in Scotland has been used for assays of both ad and ay sub-types

- The need for all RTCs to have Quality Control Officers/Managers, with suitable training, authority and status, was well recognised

- Control of test reagents made in the BTS, (by BPL Diagnostics or in RTCs) was desirable, but would probably be effected by NIBSC if regulated by a Statutory Instrument

- Control of quality of certain materials (transfusion bags and equipment) was believed to be currently the responsibility of DHSS Supplies, or of the procurement personnel. But independent QC of such items or QC auditing, should be carried out.

- Various activities (such as data collection surveys, common to the BTS), which might be centralized, are currently done by various appointed RTCs with suitable expertise and facilities. This encourages interest and enterprise among the RTCs but appropriate back-up for those centres must be available.

- The specifications for plasma sent to PF Centres should be formulated by them; the responsibility that such plasma complied with those specifications rested with the RTCs and the PF Centres

- The fact was noted that the deadline (1 March) for product liability has passed

- The style and structure of the Guidelines would be based on the WHO Requirements. A glossary of terms was needed and should be as close as possible to the terms defined by WHO.

- Dr Thomas has not yet received the amended version of the WHO Requirements from Geneva. They will be circulated when they become available. They are being updated during this year, for formal approval at WHO in October

3 Specification for validation of virus inactivation procedures
2nd draft 25.01.88 (BC)

- Various amendments were made and will be incorporated by Dr Cuthbertson

- The next version will be given to Dr P Minor (virologist NIBSC) for comment and to the WG.M after the meeting (30 March at NIBSC) on virus inactivation procedures applied to blood products

- The assay method(s) should be specified by the WG on Microbiology

- The extent to which virus inactivation and removal experiments must 'simulate' the conditions used in production is ill defined (and must probably remain so)

- It was understood that the reason why measurement of virus-associated reverse transcirptase is not considered a suitable test, when the virus identify is known, is because of its lack of sensitivity

- A statement on non A, non B Hepatitis inactivation/removal will be included

4 Specification for plasma for fractionation 1st draft (15.02.88)
Dr Cuthbertson

4.1 - Various amendments were agreed and will be incorporated by BC

4.2 - The Plasma Fractionation Laboratories receive and use single and pooled plasma of many different 'types'

- NIBSC should be asked to set up a national working standard for HBsAg tests

- The acceptable limit for HBsAg in Scotland and N Ireland is ¨0.5 iu/ml using the Wellcome and Abbot test kits. The BPL Elstree apply a limit of 1.0 iu/ml. Until a common UK standard was calibrated and used it is not certain which figure would be applied - but it must be the same throughout the UK

- HBsAg test kits are 'approved' in Scotland; no mechanism for kit testing/approval exists in England/Wales. A co-ordinated UK policy is needed, to be formulated by the BTS/NIBSC Liaison Committee

- ALT testing (for evidence of non A non B Hepatitis) may need to be implemented for plasma products for them to be competitive in the market

- A suitable British standard for ALT testing should be established, and an acceptable mean limit specified.

- The numbers of platelets in plasma sent to PFL need to be monitored from time to time

- It was expected that eventually all plasma used for preparation of Factor VIII concentrates would come from single, not pooled, donations

4.3 Plasmaphesis plasma for production of Factor VIII concentrate

- Specifications will be similar to those for single donation plasma except that higher numbers of platelets would be allowed

4.4 - These amended specifications will be sent for comment to RTCs

- Specifications must be the same throughout the UK; differences in test procedures can be specified in technical appendices

- There may be certain differences in labelling requirements, in Scotland and N Ireland, and in England and Wales

4.5 There is a need to specify guidance on expiry dates for these plasmas.

5 Factor VIII concentres. 2nd draft (Dr J Smith)

- The document gives guidance on the design and intended characteristics of the product. A set of product specifications will need to be prepared, based on this document

- Various amendments will be incorporated (by JS)

6 The next meeting should be devoted to completion of current drafts on Factor VIII and plasma, to Factor IX, and a start made on albumin.

The next meeting will be on Monday, 25 April at 10.30am at NIBSC