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POLICY DOCUMENT

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TITLE:	**POLICY FOR PREVENTION OF BATCH CROSS-CONTAMINATION WITH INFECTIVE PRIONS**

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POLICY FOR PREVENTION OF
BATCH CROSS-CONTAMINATION WITH INFECTIVE PRIONS

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POLICY FOR PREVENTION OF
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1. INTRODUCTION

At this time, there is no convincing data to suggest that prion diseases such as Creutzfeldt-jakob disease (C-JD) can be transmitted by plasma or plasma products. Nevertheless, regulatory agencies are concerned about the theoretical risk and require manufacturers to recall batches if it was found that the donor had a high risk of being infected with C-JD. PFC would be required to notify the MCA if it was found that we had fractionated plasma from a high risk C-JD donor. In addition we are now required to carry out if a recall if a donation is subsequently found to have been obtained from a donor with nvCJD.It is therefore prudent to plan on the assumption that we need to minimise the risk of cross-contamination from one pool of plasma to another at any stage of the manufacturing process. In addition,every effort will be made to ensure that donor numbers are minimised in all finished products. This will be described in more detail in another policy statement.

As we get into contract fractionation, it is also likely that regulatory bodies will require evidence of effective segregation procedures to confirm lack of cross-contamination between UK and contract plasma. This policy statement is intended to provide the basis for ensuring that this type of segregation is achieved.

2. POLICY OBJECTIVE

The objective of this policy is to carry out a step capable of inactivating C-JD on all reusable equipment and reagents. The steps which are recognised for this purpose are

- Autoclaving at 134 Deg C for 20 minutes (Procedure A). However, our current equipment may be damaged by the routine use of such conditions and an interim objective of 121 Deg C for 15 minutes will be established. This will still give substantial elimination of CJD prions.

- Treating With 1M sodium hydroxide for 1 hour (Procedure B)
- Treating with 2% hypochlorite for 1 hour (Procedure C)

This objective should be obtained as rapidly as possibly, with a proposed completion date of 1 Jan 1999.

3. POLICY IMPLEMENTATION

Existing equipment has been categorised according to ability to be treated. Based on this categorisation, the following steps will be carried out:-

3.1 All equipment which can currently be sterilised by these methods will be treated between uses. Where multiple methods can be used, autoclaving will be the treatment of choice.

3.2 All new equipment will be specified in such a way that it can be treated on installation. If necessary, ancilliary treatment equipment (e.g. SIP), will be specified as part of the purchase.

3.3 Where existing equipment or reagents cannot be treated, then there will be a gradual replacement programme, subject to available resources.

3.4 Implementation of the detail of this policy will be progressed by an internal working Group which is suitably empowered to take the necessary action consistent with the correct procedure for change control.