Change Notification UK National Blood Services  No. 21 - 2015

Leucocyte depletion of blood components - Concessionary release


The concessionary release limit for leucocyte depletion of components has been amended to improve clarity. Therefore the text of section 7.1 Leucocyte depletion must be amended as follows:

7.1   Leucocyte depletion

Please change:

‘Where statistical process monitoring methodology is not judged appropriate due to an inability to control the process or the production of small numbers of components, all components routinely issued to stock must have been shown to contain less than 1 x 10^6 leucocytes.

Issue (to stock) of components, which do not meet the leucocyte depletion specified limit, must follow a concessionary release procedure (see Section 6.10).

to:

‘Where statistical process monitoring methodology is not judged appropriate due to an inability to control the process or the production of small numbers of components, all components routinely issued to stock must have been shown to contain less than 5 x 10^6 leucocytes.

Issue (to stock) of components, which do not meet the leucocyte depletion specified limit of 5 x 10^6/unit, must follow a concessionary release procedure (see Section 6.10).

The supporting paper, JPAC 14-38 - Concessionary Release Limits for Leucocyte Depletion, leading to this Change Notification, can be found in the Document Library/Supporting Papers of the JPAC website:  http://www.transfusionguidelines.org.uk/document-library/supporting-papers

Dr Sheila MacLennan
Professional Director - Joint UKBTS Professional Advisory Committee
Direct Dial: (0113) 820 8638  sheila.maclennan@nhsbt.nhs.uk