

Joint UKBTS / NIBSC Professional Advisory Committee ⁽¹⁾ Summary Sheet

1. Paper for the JPAC meeting on:	Thursday 11 March 2010
2. Date submitted:	01 March 2010
3. Title (including version no.):	Addition to 14.5.1 of the Red Book to allow rare antisera to be used in investigations.
4. Author(s):	Malcolm James - SACIH
5. Brief summary:	Previous editions of the Red Book allowed (under controlled conditions) expired antisera to be used. The current wording could be interpreted as not allowing this and in response to specific concerns words need to be added to prevent a situation where a working example of a rare antibody cannot be used in investigations.
6. Action required by JPAC: (What do you want JPAC to do in response to this paper?) e.g. <ul style="list-style-type: none"> • endorse a specific recommendation • advise where there is a choice of possible actions • advise on priorities within the work plan • provide a steer on policy 	Endorse a specific recommendation.
7. Any other relevant information:	Suggested words attached in a separate file.

⁽¹⁾ **Joint United Kingdom Blood Transfusion Services and National Institute for Biological Standards and Control Professional Advisory Committee**

Proposal to add to section 14.5. of the Red Book 2005 Guidelines

14.5.1 (page 185) of the current Guidelines states that:

‘Where manufacturers define protocols for the preparation and storage of reagents and test kits these **should** be followed’

The 5th edition section 5.4.1. permitted expired reagents to be retained and used by utilising appropriate controls.

It is not the intention to support poor stock- keeping by stipulating that expiry dates can be ignored and the wording needs to reflect this.

Rare and sometimes irreplaceable antisera may have an expiry date and it should not be the case that the completion of a complex investigation is not possible due to a rigid regard for manufacturers instructions.

The suggested wording for 14.5.1. Is

Where manufacturers define protocols for the preparation and storage of reagents and test kits these should be followed. In situations where the use of rare antisera is required then the use of such material post-expiry should be demonstrated as appropriate by the use of controls. Using rare antisera in this way must be approved and documented by Quality Assurance.

Malcolm James 28/10/09