Guidelines for the Blood Transfusion Services

6.7: Component storage

http://aws-lon-jpac.targetservers.uk/red-book/chapter-6/6-7

6.7: Component storage

6.7.1: Specifications for component storage areas

Storage areas for blood components must operate within a specified temperature range and should provide adequate space and suitable lighting, and be arranged and equipped to allow dry, clean and orderly storage.

Good manufacturing practice requires that components of different status are appropriately identified and effectively separated.

Recognised status categories are noted below.

6.7.1.1: Quarantine

Procedures should ensure that untested components are not quarantined with components which have produced, or are likely to produce, repeatably reactive results in mandatory microbiological screening tests.

Secure and exclusive quarantine storage should be available for known biohazard material awaiting disposal (see section 6.8.2).

6.7.1.2: Non-conforming

Components which do not comply with the specification for mandatory tests or are otherwise unsuitable for transfusion should be categorised as non-conforming. Normally, such components would be discarded. However, if they are to be issued for therapeutic, reagent or research use, a concessionary release procedure must be used (see section 6.10).

6.7.1.3: Returned

Components that have been returned from areas outside the direct control of the blood supplier should not normally be returned to stock.

Components that have been returned to the blood supplier with substantive evidence that they have been stored appropriately and within specification, should be held securely pending possible reinstatement to stock by a designated person.

6.7.1.4: Stock

Only those components which have been deemed satisfactory for issue by a designated person should be held in stock (see section 6.9).

Appropriate security and status labelling of component storage areas are essential.

A current inventory should be maintained of components in each storage category/area.

Areas/equipment in which components are to be stored should be validated before their introduction into routine use and checked for calibration to a documented schedule thereafter.

A permanent, continuous record of storage temperatures should be made, reviewed and stored. There should be a log of alarm events that describes the corrective actions taken.

6.7.2: Procedures for component storage

Written procedures must be established for the storage of blood components. These should include the following:

- a procedure to ensure components are not released to stock unless authorised by a designated person (see section 6.7.1.4)
- definitions of the designated storage areas including the storage specification, the status of components to be stored in each area and the persons who are authorised to access each specific area
- procedures for validating and monitoring the conditions of storage
- procedures for ensuring the good order and cleanliness of storage areas
- procedures to ensure the storage of blood components does not jeopardise their identity, integrity or quality
- a procedure which ensures appropriate stock rotation.