Guidelines for the Blood Transfusion Services

21.1: General considerations

http://www.transfusionguidelines.org/red-book/chapter-21/21-1-general-considerations

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Tissue Establishments should have dedicated processing and storage facilities designed and be operated to prevent contamination, cross-contamination, mislabelling and deterioration of tissues.

All processes which affect the safety or quality of tissues must be validated.

21.1.1: Equipement - retrieval/processing

All equipment which affects the safety or quality of tissues must be validated.

Where possible single-use instruments must be used.

If it is impractical or not possible to use single-use instruments and reusable equipment has to be used, then the use must be risk assessed to ensure that all required mitigating actions are considered. Tissue Establishment reusable instruments and other items which come into direct contact with donor tissue during retrieval and processing must be thoroughly washed and sterilised between uses. These must be fully traceable to the individual tissue donor/batch and allow tracking through decontamination, sterilisation and use. These instruments should be washed and sterilised according to NHS Estates Health Technical Memoranda (HTM) 01-01,[1] 2030[2] and 2031[3] Instruments must not be allowed to dry out before washing prior to sterilisation. Prompt removal of residual blood and tissues is an important aspect of decontamination, particularly with regard to removal of prions.

21.1.2: Incoming materials and solutions

All purchased materials and solutions which could affect the tissue quality and safety must be inspected on receipt to ensure compliance with specification.

21.1.3: Use of third parties

UK Blood Transfusion Services Tissue Establishments may use third parties to perform tissue retrieval, (including eye retrieval), processing steps such as irradiation, tissue evaluation such as bacterial tests, quality control tasks such as environmental monitoring or tissue storage, transport and distribution. Tissue storage beyond 48 hours can only be undertaken at a premises directly licensed under the Q&S Regulations. Storage >48h cannot be undertaken at the premises of an unlicensed third party. Wherever such tasks are performed by or on behalf of a third party, this must be subject to a written agreement between the parties involved. This must specify the processes to be performed, the applicable standards and specifications, and the responsibilities of both parties in achieving the desired outcome. The processes should be performed, as a minimum, in accordance with the guidance referenced from Chapter 19.

21.1.4: Tissue contamination

In the event of a healthcare worker sustaining an injury such that his/her blood comes into contact with the tissue, the tissue must be discarded.