HTA Guidance – for tissue establishments in Northern Ireland only

Assessment tool to demonstrate that imported tissues and cells meet equivalent standards of quality and safety to those required by The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (the Regulations).

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| **Importers must be able to verify equivalent standards of quality and safety after reading the relevant Directive.****Please ensure that these key points are considered and that the information that is used to ensure equivalence is explicit in these aspects.** | **Please state how the assurance mechanism can be used to demonstrate equivalent standards of quality and safety of an imported unit from 3CS. A combination of the following may be used: an agreement with the 3CS, accreditation, supplementary information requested from 3CS.** |
| **Quality and safety requirements specified by Directive 2006/17/EC:** |
| **Donor evaluation** |
| **1. Donor Selection** |
| 1. Donors that do not meet the criteria in Annex I are excluded unless justified on the basis of a documented risk assessment.
2. Allogeneic living donors are selected on the basis of their health and medical history, provided on a questionnaire and through an interview performed by a qualified and trained health professional.
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| **2. Laboratory tests required for donors** |
| 1. The mandatory minimum biological tests are carried out required by Annex II.
2. The test must be carried out by a qualified laboratory. The type of test used must be validated for the purpose according with current scientific knowledge.
3. The time that blood samples are obtained from the donor in relation to the donation must be appropriate for the type of tissues or cells procured.
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| **Procurement** |
| **3. Consent and donor identification** |
| 1. It is good practice to obtain consent in the source country and importers should satisfy themselves that consent is part of the process within the source country by which the tissues and cells are obtained.
2. Donors have been reliably identified.
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| **4. Procurement procedures for tissues and cells** |
| 1. The procurement procedures must protect those properties of the tissues and cells that are required for their ultimate clinical use, and at the same time minimise the risk of microbiological contamination during the process, particularly when tissues and cells cannot subsequently be sterilised.
2. Sterile instruments and devices must be used for tissues and cells procurement. Instruments and devices must be of good quality, validated or specifically certified and regularly maintained for the procurement of tissues and cells.
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| **5. Donor documentation** |
| 1. Donor records required by Annex IV 1.4.1 (a) to (h) must be available.
2. A procurement report containing the information required by Annex IV 1.4.2 (a) to (g) must be produced.
3. Donor records required for full traceability must be kept for a minimum of 30 years after clinical use, or the expiry date, in an appropriate archive.
4. The complete donor records must be reviewed and assessed for suitability and signed by a qualified health professional.
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| **6. Packaging** |
| 1. Following procurement, all recovered tissues and cells must be packaged in a manner which minimises the risk of contamination and must be stored at temperatures that preserve the required characteristics and biological function of the tissues or cells.
2. The packaged tissues or cells must be shipped in a container which is suitable for the transport of biological materials and which maintains the safety and quality of the contained tissues or cells.
3. Any accompanying tissue or blood samples for testing must be accurately labelled to ensure identification with the donor, and must include a record of the time and place the specimen was taken.
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| **7. Labelling of the procured tissues and cells** |
| 1. At the time of procurement, every package containing tissues and cells must be labelled. The primary tissues or cells container must indicate the donation identification or code and the type of tissues or cells.
2. The additional information required by Annex IV point 1.6 (a) to (e) must also be included either on the label or on a separate sheet accompanying the primary package.
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| **8. Labelling of the shipping container** |
| 1. Shipping containers must be labelled with the information required by Annex IV point 1.7 (a) to (i).
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| **Quality and safety requirements specified by Directive 2006/86/EC:** |
| **Processing** |
| **9. Equipment and materials** |
| 1. All critical equipment and technical devices must be identified and validated, regularly inspected and preventively maintained in accordance with the manufacturers' instructions.
2. Where equipment or materials affect critical processing or storage parameters (e.g. temperature, pressure, particle counts, microbial contamination levels), they must be identified and must be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with a critical measuring function must be calibrated against a traceable standard if available.
3. The procedures for the activities must detail the specifications for all critical materials and reagents.
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| **10. Facilities/premises** |
| 1. When activities include processing of tissues and cells while exposed to the environment, this must take place in an environment with specified air quality and cleanliness in order to minimise the risk of contamination, including cross-contamination between donations. The effectiveness of these measures must be validated and monitored.
2. Where tissues or cells are exposed to the environment during processing, without a subsequent microbial inactivation process, an air quality with particle counts and microbial colony counts equivalent to those of Grade A as defined in the current European Guide to Good Manufacturing Practice (GMP), Annex 1 and Directive 2003/94/EC is required with a background environment appropriate for the processing of the tissues or cells concerned but at least equivalent to GMP Grade D in terms of particles and microbial counts.
3. When the activities involve storage of tissues and cells, the storage conditions necessary to maintain the required tissues and cells properties, including relevant parameters such as temperature, humidity or air quality must be defined.
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| **11. Processing Validation** |
| 1. The critical processing procedures must be validated and must not render the tissues or cells clinically ineffective or harmful to the recipient.
2. The processing procedures must undergo regular critical evaluation to ensure that they continue to achieve the intended results.
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| **12. Storage and release** |
| 1. Records must demonstrate that before tissues and cells are released all appropriate specifications are met, in particular all current declaration forms, relevant medical records, processing records and test results have been verified according to a written procedure by a person authorised for this task.
2. For every critical activity, the materials, equipment and personnel involved must be documented.
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| **13. Distribution and recall** |
| 1. Critical transport conditions, such as temperature and time limit must be defined to maintain the required tissues and cells properties.
2. The container/package must be secure and ensure that the tissues and cells are maintained in the specified conditions. All containers and packages need to be validated as fit for purpose.
3. An effective recall procedure must be in place, including a description of the responsibilities and actions to be taken.
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| **14. Final labelling for distribution** |
| 1. The primary tissues or cells container must provide the details required by Annex II E 1 points (a) to (f).
2. The primary tissues or cells container or accompanying documentation must provide the information required by Annex II E 2 points (a) to (i).
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| **15. External labelling of the shipping container** |
| 1. The primary container must be placed in a shipping container and labelled with the information required by Annex II F points (a) to (f).
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| **16. Notification of serious adverse events** |
| 1. There must be procedures in place to retain the records and to notify tissue establishments without delay of any serious adverse events associated with any activity which may influence the quality and/or safety of human tissues and cells.
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