Guidelines for the Blood Transfusion Services

Chapter 27: Specification for labelling consumables used in therapeutic product production

http://transfusionguidelines.org/red-book/chapter-27-specification-for-labelling-consumables-used-in-therapeutic-product-production

Chapter 27: Specification for labelling consumables used in therapeutic product production

27.1: Introduction

This chapter defines the requirements of the UK Blood Transfusion Services for the labelling by the manufacturer of 'stand-alone' consumable medical devices (critical consumables) used in the production of therapeutic blood components and tissues.

These devices are distinct from blood bags (either individual bags or within a blood pack or apheresis set assembly, including those pre-filled with anticoagulant or preservatives) that are described in Chapter 26 and tissue containers which are described in Chapter 24.

This specification applies to:

- stand-alone intravenous (IV) and other solutions including:
  - preservatives and additives (e.g. platelet additive solution)
  - saline
  - dextrose and dextran
  - anticoagulants
  - pathogen inactivators
- filters (e.g. leucodepletion, prion filtration)
- fluid transfer sets
- injection sites, clamps, one-way valves.

27.2: Specification

All critical consumables used in the manufacture of therapeutic product that either come into contact with the therapeutic or influence its quality or the safety of recipients must be CE-marked medical devices (93/42 /EEC).[1]

Where a harmonised European standard exists for such devices this is the preferred route for conformity assessment. A list of 'reference harmonised' EU standards is to be found at the European Commission Enterprise and Industry website.[2]

Labelling of critical consumables and their packaging shall comply with the EU Medical Devices Directive[1] and appropriate harmonised standards.

The critical consumable or, when there is insufficient space, its individual overwrap must bear the following information:

- The ‘CE’ mark and the registration number.
- The name and address of the manufacturer.
- The manufacturer’s catalogue number (product code) and lot or batch number in eye-readable and preferably also barcode format (see below).
- On all products, the words or approved medical device symbol(s) shown in Figure 26.2:
    - Do not re-use this container
    - Sterile
    - Do not use if damaged/deteriorated
    - Expiry date (see note below)
    - Refer to instructions for use.

Note: The expiry date may be expressed as: ‘Do not use after DD/MM/YY’ where DD is the day number, MM the month number and YY the year. For clarity, the expiry date will be midnight (23:59 hours) on the date shown. It is permissible to use only MM/YY; in this instance the expiry date will be midnight on the last day of the month/year shown.

The expiry date may alternatively be provided by the manufacturer on the immediate overwrap in which case the following statement must be applied to the base label: ‘Use within x days of opening the immediate overwrap’ where x is the number of days validated by the manufacturer.

Containers for intravenous solutions must in addition bear the following information on each container:

- the nominal volume
- the formulation (in English) of the solution
- the words or approved medical device symbol(s) shown in Figure 26.2:
    - Do not vent
    - Contains phthalate (DEHP) (if applicable)
    - Pyrogen free fluid pathway (when applicable)
- Manufacturers should, when appropriate, indicate that the material of the container including its sub-components are latex free. The symbol in Figure 26.2 may be used.

Label adhesives applied directly to the surface of a critical consumable that may come into contact with blood or tissue must be tested and approved by manufacturers in accordance with the relevant current versions from the ISO 10993 biocompatibility series of standards (or equivalent national standards). The risk of the adhesive coming into contact with blood or tissue should be established by ‘extractables’ testing (ISO 10993 – Parts 1, 17 and 18). If testing reveals an unacceptable level of migration, biocompatibility testing should be extended to interaction with blood (ISO 10993 – Part 4) and toxicological testing (ISO 10993 – Parts 3 and 5).

- ISO 10993-1:2009 Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process

- ISO 10993-3:2003 Biological evaluation of medical devices. Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4:2002/Amd 1:2006 Biological evaluation of medical devices. Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 Biological evaluation of medical devices. Part 5: Tests for in vitro cytotoxicity
- ISO 10993-17:2002 Biological evaluation of medical devices. Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18:2005 Biological evaluation of medical devices. Part 18: Chemical characterisation of materials.

27.3: Manufacturers' catalogue and lot numbers

Below we refer to a convention (ISBT 128) for encoding the manufacturer's catalogue and lot numbers. ISBT 128 is recognised by the UK Blood Transfusion Services which are progressing towards full compliance for their therapeutic products and associated critical consumables.

27.3.1: ISBT 128 manufacturers' blood pack catalogue and lot numbers

To achieve ISBT 128 compliance the UK Blood Transfusion Services will adopt the ISBT 128 convention for the manufacturer's catalogue and lot number barcodes on critical consumables. ISBT 128 codes the manufacturer's identity and catalogue number in one barcode and the lot number in a separate barcode. For ISBT, both the catalogue and lot number are required to uniquely identify a batch of critical consumables.

Full details are provided in the current version of ISBT 128 Standard Technical Specification, which is available on the ICCBBA website (www.iccbba.org). The following data structures apply:

- For stand-alone containers of intravenous solution and other critical consumables: Data Structures 021 and 022.

27.4: References

1. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. *OJ*, L 169, 12.7.1993, pp1–43.

2. References of harmonised standards and of other European standards can be found at http://ec.europa.eu/enterprise/policies/european-standards/index_en.htm