

Guidelines for the Blood Transfusion Services

2.1: Introduction

<http://transfusionguidelines.org/red-book/chapter-2-quality-in-blood-and-tissue-establishments-and-hospital-blood-banks/2-1-introduction>

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The key requirements for Blood Establishments and for hospital blood banks are defined in the Blood Safety and Quality Regulations (Statutory Instrument 2005 No. 50) as amended,¹ and are enforced by the Medicines and Healthcare products Regulatory Agency (MHRA). Those for tissues and cells are defined in the Human Tissue (Quality and Safety for Human Application) Regulations, 2007 (Statutory Instrument 2007 No. 1523),² and are enforced by the Human Tissue Authority (HTA).

These regulations require that Blood and Tissue Establishments are licensed and subject to regular inspection for compliance. Hospital blood banks are not formally licensed but must submit annual compliance reports to the MHRA. Based on these compliance reports, the MHRA select a number of hospital blood banks for inspection every year and can also decide to do 'for cause' inspections when there is evidence of non-compliance.

The MHRA and HTA have powers to remove licences from Blood and Tissue Establishments, respectively, and the MHRA can issue cease and desist orders to prevent blood banks from continuing in operation. These powers derive from the relevant UK legislation, which is designed to ensure that appropriate standards of performance are achieved and maintained. This inspection process is designed to generate a climate of continual quality improvement, and this chapter will look at the key issues which have to be addressed in achieving an effective quality management system.