

---

STATUTORY INSTRUMENTS

---

**2020 No. 1304**

**The Blood Safety and Quality  
(Amendment) (EU Exit) Regulations 2020**

**Amendment of regulation 7**

7. In regulation 7—

(a) for paragraph (a) substitute—

“(a) for paragraph (1)(b) substitute—

“(b) establish and maintain a quality system for blood establishments—

(i) in relation to Great Britain, that is based on the principles of good practice, which meets the standards and requirements set out in the Annex to Commission [Directive 2005/62/EC](#) and which gives effect to the Good Practice Guidelines for Blood Establishments Required to Comply with [Directive 2005/62/EC](#) published in the 20th edition of the Guide to the preparation, use and quality assurance of blood components<sup>(1)</sup>;

(ii) in relation to Northern Ireland, that is based on the principles of good practice, which complies with the Community standards and requirements set out in the Annex to Commission [Directive 2005/62/EC](#) and which gives effect to the requirements in respect of the use of good practice guidelines set out in Article 2.2 of that Directive;”;

(b) in paragraph (1A) inserted by paragraph (b), for the words “For the purposes of” substitute “In relation to Great Britain, for the purposes of”.

---

<sup>(1)</sup> [https://www.edqm.eu/sites/default/files/medias/fichiers/Blood/good\\_practices\\_guidelines\\_for\\_blood\\_establishments-blood\\_guide\\_20th\\_may\\_2020.pdf](https://www.edqm.eu/sites/default/files/medias/fichiers/Blood/good_practices_guidelines_for_blood_establishments-blood_guide_20th_may_2020.pdf). Hard copies may be obtained from the Ministerial Correspondence and Public Enquiries Unit, Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU.