
STATUTORY INSTRUMENTS

2019 No. 4

**The Blood Safety and Quality
(Amendment) (EU Exit) Regulations 2019**

9. In regulation 9—

[^{F1}(a) for paragraph (1)(b) substitute—

“(b) establish and maintain a quality system for the hospital blood bank—

(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;

(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) after paragraph (1) insert—

“(1A) [^{F2}In relation to Great Britain, for the purposes of] paragraph (1)(b), references to the competent authority or to competent authorities in the Annex to that Directive must be read as references to the Secretary of State.”.

Textual Amendments

F1 Reg. 9(a) substituted (31.12.2020 immediately before IP completion day) by [The Blood Safety and Quality \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1304\)](#), regs. 1, **8(a)**

F2 Words in reg. 9(b) substituted (31.12.2020 immediately before IP completion day) by [The Blood Safety and Quality \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1304\)](#), regs. 1, **8(b)**

Commencement Information

I1 Reg. 9 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

Changes to legislation:

There are currently no known outstanding effects for the The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019, Section 9.