
DRAFT STATUTORY INSTRUMENTS

2020 No.

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

Substitution of regulation 12

12. For regulation 12 substitute—

“**12.**—(1) In regulation 23—

- (a) at the end of the heading insert “in relation to Great Britain”;
- (b) in paragraph (1), for the words from “he shall” to the end of that paragraph substitute “the Secretary of State must, in relation to Great Britain, notify blood establishments that those criteria must be adopted.”.

(2) After regulation 23 insert—

“Specific epidemiological situations in relation to Northern Ireland

23ZA.—(1) Where the Secretary of State is aware of a specific epidemiological situation, such as an outbreak of a disease, which may affect the safety of blood donations, and as a result of which the Secretary of State considers that specific deferral criteria for the collection of blood donations should be adopted, the Secretary of State must in relation to Northern Ireland—

- (a) notify blood establishments that those criteria must be adopted; and
- (b) notify the Commission of—
 - (i) the epidemiological situation; and
 - (ii) the additional deferral criteria which blood establishments are required to adopt in relation to it pursuant to sub-paragraph (a).

(2) A blood establishment shall adopt and comply with any criteria for additional tests notified to them by the Secretary of State pursuant to paragraph (1).”.