Blood establishment requirements

7.—(1) A blood establishment shall—
    (a) ensure that the personnel directly involved in the collection, testing, processing, storage and distribution of human blood and blood components for the blood establishment are qualified to perform those tasks and are provided with timely, relevant and regularly updated training;
    (b) establish and maintain a quality system for blood establishments based on the principles of good practice;
    (c) ensure that all testing and processes of the blood establishment which are referred to in Parts 2 to 5 of the Schedule are validated;
    (d) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available for inspection under regulation 15;
    (e) notify the Secretary of State of—
        (i) any serious adverse events related to the collection, testing, processing, storage and distribution of blood and blood components by the blood establishment which may have an influence on their quality and safety, and
        (ii) any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components collected, tested, processed, stored or distributed by the blood establishment; and
    (f) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood components associated with any notification referred to in paragraph (e).

(2) A blood establishment shall, in relation to the donation of blood—
    (a) give all prospective donors of blood or blood components information in accordance with Part A of Part 2 of the Schedule;
    (b) obtain from all persons who are willing to provide blood or blood components, information in accordance with Part B of Part 2 of the Schedule;
    (c) put and keep in place procedures for the evaluation of donors;
    (d) apply eligibility criteria for all donors of blood and blood components in accordance with Part 3 of the Schedule;
    (e) maintain records of the results of donor evaluations and report to donors any relevant abnormal findings from the evaluations;
    (f) ensure that—
        (i) an examination of the donor, including an interview, is carried out before any donation of blood or blood components,
(ii) a qualified health professional is responsible for giving to and gathering from donors the information which is necessary to assess their eligibility to donate, and

(iii) on the basis of that information, a qualified health professional assesses the eligibility of all donors to donate; and

(g) encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are, in so far as possible, provided from such donations, in particular, by—

(i) disseminating information about blood donation, and

(ii) advertising for blood donors.

(3) A blood establishment shall ensure that, in relation to the blood and blood components which it collects, processes, stores or distributes—

(a) each donation of blood and blood components (including blood and blood components which are imported into the European Community) is tested in conformity with—

(i) the basic testing requirements for whole blood and apheresis donations, specified in paragraph (7), and

(ii) any additional tests which may be necessary for specific components, types of donors or epidemiological situations;

(b) the storage, transport and distribution conditions of blood and blood components comply with the requirements of Part 4 of the Schedule; and

(c) quality and safety requirements for blood and blood components meet the standards specified in Part 5 of the Schedule.

(4) A blood establishment shall, in relation to the activities specified in regulation 3(2) for which it is responsible, maintain records, for a minimum period of 15 years, of—

(a) the information specified in paragraphs (5) and (6),

(b) the conduct of the tests referred to in paragraph (3)(a).

(5) The information specified in this paragraph is—

(a) the total number of donors who give blood and blood components;

(b) the total number of donations;

(c) an updated list of the hospital blood banks which it supplies;

(d) the total number of whole donations not used;

(e) the number of each component produced and distributed;

(f) the incidence and prevalence of transfusion transmissible infectious markers in donors of blood and blood components;

(g) the number of product recalls; and

(h) the number of serious adverse events and serious reactions reported;

(6) The information specified in this paragraph is—

(a) information provided to donors by the blood establishment in accordance with paragraph (2)(a);

(b) information obtained from donors by the blood establishment in accordance with paragraph (2)(b); and

(c) information relating to the suitability of blood and plasma donors in accordance with the eligibility criteria specified in Part 3 of the Schedule.
(7) The basic testing requirements with which blood establishments must ensure compliance pursuant to paragraph (3)(a)(i) are—

(a) testing to establish ABO Group, except in respect of plasma intended only for fractionation;
(b) testing to establish Rh D Group, except in respect of plasma intended only for fractionation; and
(c) testing for the following infections of donors—
   (i) Hepatitis B (HBs-Ag);
   (ii) Hepatitis C (Anti-HCV);
   (iii) HIV 1 and 2 (Anti-HIV 1 and 2).

(8) The Secretary of State may issue guidance as to the additional tests referred to in paragraph (3) (a)(ii) which are necessary in relation to specific components, types of donor or epidemiological situations and blood establishments shall have regard to such guidance.

(9) As soon as practicable after the end of the reporting year, each blood establishment shall provide to the Secretary of State a report specifying—

(a) the information referred to in paragraph (3) for that year; and
(b) details of the steps it has taken during that year to comply with paragraph (2)(g).