

## SCHEDULE 2

Regulation 23

### AMENDMENTS TO THE 1995 REGULATIONS

1. In regulation 2 of the 1995 Regulations (interpretation)—
  - (a) after the definition of “the 1994 Regulations” there shall be inserted the following definitions—
    - ““the 1998 Directive” means Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices;
    - “the 2000 Regulations” means the *In Vitro* Diagnostic Medical Devices Regulations 2000;” and
  - (b) after the definition of “half day” there shall be inserted the following definition—
    - ““*in vitro* diagnostic medical device” has the same meaning as in the 2000 Regulations;”.
2. After regulation 6 of the 1995 Regulations (withdrawals) there shall be inserted the following regulations—

#### **“Fees in connection with the registration of devices and changes to registration details**

7. Any person required to supply the Secretary of State with any information under regulation 14 of the 1994 Regulations shall, in respect of the processing of that information with regard to the possible registration of devices by the Secretary of State or possible changes to registration details, pay to the Secretary of State a fee of £70, and that fee—

- (a) shall be payable when the information is supplied by that person to the Secretary of State; and
- (b) shall accompany that information when it is supplied.

(2) Any person required to supply the Secretary of State with any information under regulation 14 of the 2000 Regulations shall, in respect of the processing of that information with regard to the possible registration of *in vitro* diagnostic medical devices by the Secretary of State or possible changes to registration details, pay to the Secretary of State a fee of £70, and that fee—

- (a) shall be payable when the information is supplied by that person to the Secretary of State; and
- (b) shall accompany that information when it is supplied.

#### **Fees payable in connection with the designation of UK notified bodies under regulation 15 of the 2000 Regulations**

8.—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 15(1) of the 2000 Regulations shall, in connection with that application for designation, pay to the Secretary of State—

- (a) if it is the second or subsequent such application and the application is being made only to address the grounds for rejection of a previous application, a fee of £650;
- (b) in all other cases, a fee of £2,600.

(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 15(4) of the 2000 Regulations of the tasks that the body may carry out shall, in connection with that application for a variation, pay to the Secretary of State a fee of £1,300.

*Status: This is the original version (as it was originally made).*

(3) Where, pursuant to regulation 15(7) of the 2000 Regulations the Secretary of State inspects premises for the purposes of deciding whether or not a body is one in respect of which the criteria set out in Annex IX of the 1998 Directive are met, the body shall pay to the Secretary of State—

- (a) in respect of an initial inspection pursuant to regulation 15(7)(a) of those Regulations, a fee of £3,200, plus—
  - (i) an amount for time spent by a member of staff out of the office while undertaking a site visit (to include time spent travelling) at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate of £51.39 per hour for time spent travelling,
  - (ii) the actual costs of travel, accommodation and subsistence, and
  - (iii) out of pocket expenses;
- (b) in respect of any other inspection pursuant to regulation 15(7)(a) of those Regulations, a fee of £2,600, plus—
  - (i) an amount for time spent by a member of staff out of the office while undertaking a site visit (to include time spent travelling) at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate of £51.39 per hour for time spent travelling,
  - (ii) the actual costs of travel, accommodation and subsistence, and
  - (iii) out of pocket expenses; and
- (c) in respect of an inspection pursuant to regulation 15(7)(b) of those Regulations, a fee of £2,600, plus—
  - (i) an amount for time spent by a member of staff out of the office while undertaking a site visit (to include time spent travelling) at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate of £51.39 per hour for time spent travelling,
  - (ii) the actual costs of travel, accommodation and subsistence, and
  - (iii) out of pocket expenses.
- (4) A fee under this regulation—
  - (a) in connection with an application—
    - (i) shall be payable when the application to the Secretary of State is made, and
    - (ii) shall accompany the application when it is made;
  - (b) in connection with an inspection, shall be payable within one month of receipt by the body of a written notice from the Secretary of State requiring payment of the fee.

### **Unpaid fees**

9. All unpaid sums due by way of, or on account of, any fees payable under these Regulations are recoverable as debts due to the Crown.

### **Waiver, reductions and refunds**

10. The Secretary of State may—

- (a) waive payment of any fee or reduce any fee or part of a fee otherwise payable under these Regulations;
  - (b) refund the whole or part of any fee paid pursuant to these Regulations.”.
- 3.** In the Table set out in the Schedule to the 1995 Regulations<sup>(1)</sup>, in the entries in Column 3—
- (a) for the words “the rate of”, at each place where they occur, there shall be substituted the words “a rate, for the time spent on site, of”; and
  - (b) after the words “any one date,” at each place where they occur, there shall be added the words “and at a rate of £51.39 per hour for time spent travelling.”.

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<sup>(1)</sup> Amended by regulation 2 of S.I.1997/694.