
STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART VI

Fees charged by the Secretary of State

Fees payable in connection with the designation etc. of UK notified bodies

54.—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 45 as a notified body 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 [^{F1}£960]; or
- (b) in all other cases, a fee of [^{F2}£3,840].

(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 45(4) 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 [^{F3}£1,880].

(3) Where, pursuant to regulation 45(7) 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 8 of Directive 90/385, Annex XI of Directive 93/42^{F4}, read with article 4 of Directive 2003/32] or Annex IX of Directive 98/79 are met, or for the purposes of deciding whether or not a body is capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, the body shall pay to the Secretary of State—

- [^{F5}(a) in respect of an initial inspection pursuant to regulation 45(7)(a), a fee of [^{F6}£4,670] plus the amounts specified in paragraph (3A);
- (b) in respect of an inspection pursuant to regulation 45(7)(a), other than an initial inspection—
 - (i) if the inspection is for the purposes of deciding whether or not the body is one in respect of which the criteria set out in all three of the Annexes referred to in this paragraph are met, a fee of [^{F7}£7,670],
 - (ii) if the inspection is for the purpose of deciding whether or not the body is one in respect of which the criteria set out in only two of the three Annexes referred to in this paragraph are met, a fee of [^{F8}£5,760], or
 - (iii) if the inspection is for the purposes of deciding whether or not the body is one in respect of which the criteria set out in only one of the Annexes referred to in this paragraph are met, or for the purposes of deciding whether or not a body is capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, a fee of [^{F9}£3,840],

plus the amounts specified in paragraph (3A); and

Status: Point in time view as at 01/04/2010. This version of this provision has been superseded.

Changes to legislation: The Medical Devices Regulations 2002, Section 54 is up to date with all changes known to be in force on or before 13 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (c) in respect of an inspection pursuant to regulation 45(7)(b), a fee of [^{F10}£3,840] plus the amounts specified in paragraph (3A).]

[^{F11}(3A) Subject to paragraph (3B), the additional amounts payable in respect of an inspection referred to in paragraph (3) shall be—

- (a) an amount for time spent by a member of staff undertaking a site visit at a rate—
- (i) for the time spent on site, of [^{F12}£271] 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
 - (ii) for the time spent travelling to and from the site, of [^{F13}£75.24] per hour;
- (b) the actual costs of travel, accommodation and subsistence; and
- (c) out of pocket expenses.

(3B) Where the Secretary of State conducts an inspection referred to in paragraph (3)(a) on the same date and at the same premises as an inspection pursuant to regulation 48(7)(a)—

- (a) the amount referred to in paragraph (3A)(3) shall include an amount for any time spent on site by a member of staff which is attributable to the conduct of the inspection pursuant to regulation 48(7)(a), at the rate referred to paragraph (3A)(a)(i); and
- (b) the costs and expenses referred to in paragraph (3A)(b) and (c) shall include any additional costs and expenses attributable to the conduct of the inspection pursuant to regulation 48(7)(a).]

(4) A fee under this regulation—

- (a) in connection with an application for designation under regulation 45(1) or a variation under regulation 45(4)—
- (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 pursuant to regulation 45(7), 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.

Textual Amendments

- F1** Sum in reg. 54(1)(a) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(2)(a)(i)**
- F2** Sum in reg. 54(1)(b) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(2)(a)(ii)**
- F3** Sum in reg. 54(2) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(2)(b)**
- F4** Words in reg. 54(3) inserted (1.9.2003) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **16**
- F5** Reg. 54(3)(a)-(c) substituted (1.4.2007) by The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007 (S.I. 2007/803), regs. 1(1)(b), **13(2)(c)**
- F6** Sum in reg. 54(3)(a) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(2)(c)(i)**
- F7** Sum in reg. 54(3)(b)(i) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(2)(c)(ii)**
- F8** Sum in reg. 54(3)(b)(ii) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(2)(c)(iii)**
- F9** Sum in reg. 54(3)(b)(iii) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(2)(c)(iv)**

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- F10** Sum in reg. 54(3)(c) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(2)(c)(v)**
- F11** Reg. 54(3A)(3B) inserted (1.4.2007) by The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007 (S.I. 2007/803), regs. 1(1)(b), **13(2)(d)**
- F12** Sum in reg. 54(3A)(a)(i) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(2)(d)(i)**
- F13** Sum in reg. 54(3A)(a)(ii) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(2)(d)(ii)**

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