STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART VI

Fees charged by the Secretary of State

Interpretation of Part VI

52.—(1) In this Part[F1]...—

"Group A device" means a Class I medical device, a Class IIa medical device, or a Class IIb medical device which is neither an implantable device nor a long term invasive medical device;

"Group B device" means a Class IIb medical device which is either an implantable medical device or a long term invasive medical device, or a Class III medical device, or an active implantable medical device; and "half day" means a period of three and a half hours.

(2) For the purposes of this Part, medical devices are classified as being implantable or long term invasive medical devices in accordance with the definitions set out in Section 1 of Annex IX of Directive 93/42, and in the event of a dispute over the classification of a device, the Secretary of State shall determine the classification of the device in accordance with the definitions set out in Section 1 of Annex IX of Directive 93/42.

Textual Amendments

F1 Words in reg. 52(1) omitted (1.9.2003) by virtue of The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **15**

Fees in connection with the registration of devices and changes to registration details E+W+S

53. Any person required to supply the Secretary of State with any information under **[**[F2]regulation 7A, 19, 21A, 33A or 44**]** shall, in respect of the processing of that information with regard to the possible registration of that person by the Secretary of State or possible changes to his registration details, pay to the Secretary of State a fee of **[**[F3]£100**]**, 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.

Extent Information

E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F2 Words in reg. 53 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(2)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**

F3 Sum in reg. 53 substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **2**

Fees in connection with the registration of devices and changes to registration details N.I.

53. Any person required to supply the Secretary of State with any information under regulation 19 **[**F58, 21B**]** or 44 shall, in respect of the processing of that information with regard to the possible registration of that person by the Secretary of State or possible changes to his registration details, pay to the Secretary of State a fee of **[**F59£100**]**, 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.

Extent Information

E5 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F58 Word in reg. 53 inserted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 20**

F59 Sum in reg. 53 substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **2**

[F4**Fees payable in connection with the designation of approved bodies]** E+W+S

54.—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 45 as **[**F5an approved 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 **[**F6£2,063**]**; or

(b) in all other cases, a fee of **[**F7£8,252**]**.

(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 **[**F8£6,504**]**.

(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, **[**F9both read with Regulation (EU) No 722/2012**]** 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 **[**F10a mutual recognition agreement**]** which it needs to be able to fulfil, the body shall pay to the Secretary of State—

[F11(a) in respect of an initial inspection pursuant to regulation 45(7)(a), a fee of **[**F12£15,904**]** 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 **[**F13£10,160**]**,

(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 **[**F13£10,160**]**, 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 **[**F10a mutual recognition agreement**]** which it needs to be able to fulfil, a fee of **[**F13£10,160**]**,

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

(c) in respect of an inspection pursuant to regulation 45(7)(b), a fee of **[**F14£4,404**]** plus the amounts specified in paragraph (3A).**]**

[F15(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 **[**F16£361.20**]** 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 **[**F17£90.30**]** 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).**]**

[F18(3C) **[**F19An approved body**]** that applies to the Secretary of State for a renewal of its designation pursuant to article 4 of Regulation (EU) No 920/2013 shall pay to the Secretary of State—

(a) a fee of £8,252 in respect of the application; and

(b) where an audit is carried out in connection with the application, a fee of £15,904 in respect of the audit.

(3D) Where the Secretary of State conducts an assessment of **[**F20an approved body**]** pursuant to article 5 of Regulation (EU) No 920/2013, **[**F21the approved body**]** shall pay to the Secretary of State—

(a) if the assessment relates to the UK notified body's assessment of clinical data only, a fee of £2,586; or

(b) in any other case, a fee of £3,876.

(3E) **[**[F22]An approved body**]** that submits a summary evaluation report to the Secretary of State pursuant to article 5(4) of Regulation (EU) No 722/2012 shall pay to the Secretary of State a fee of £532.**]**

(4) A fee under this regulation—

(a) in connection with an application for designation under **[**[F23]regulation 45(1),**]** a variation under regulation 45(4)**[**[F24], a renewal under Regulation (EU) No 920/2013 (but not any associated audit) or a submission of a summary evaluation report under Regulation (EU) No 722/2012**]**—

(i) shall be payable when the application **[**[F25]or submission**]** to the Secretary of State is made, and

(ii) shall accompany the application **[**[F26]or submission**]** when it is made;

(b) in connection with an inspection pursuant to regulation 45(7) **[**[F27]or an audit or assessment pursuant to Regulation (EU) No 920/2013**]**, 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.

[[F28](5) In this regulation, "Regulation (EU) No 920/2013" means Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices.**]**

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F4 Reg. 54 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(3)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**

F5 Words in reg. 54(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(3)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**

F6 Sum in reg. 54(1)(a) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(2)(a)**

F7 Sum in reg. 54(1)(b) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(2)(b)**

F8 Sum in reg. 54(2) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(3)**

F9 Words in reg. 54(3) substituted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **16**

F10 Words in reg. 54(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(3)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**

F11 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)**

F12 Sum in reg. 54(3)(a) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(4)(a)**

F13 Sum in reg. 54(3)(b) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(4)(b)**

F14 Sum in reg. 54(3)(c) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(4)(c)**

F15 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)**

F16 Sum in reg. 54(3A)(a)(i) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(5)(a)**

F17 Sum in reg. 54(3A)(a)(ii) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(5)(b)**

F18 Reg. 54(3C)-(3E) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(6)**

F19 Words in reg. 54(3C) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(3)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**

F20 Words in reg. 54(3D) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(3)(e)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**

F21 Words in reg. 54(3D) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(3)(e)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**

F22 Words in reg. 54(3E) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(3)(f)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**

F23 Words in reg. 54(4)(a) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(i)**

F24 Words in reg. 54(4)(a) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(ii)**

F25 Words in reg. 54(4)(a)(i) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(iii)**

F26 Words in reg. 54(4)(a)(ii) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(iii)**

F27 Words in reg. 54(4)(b) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(b)**

F28 Reg. 54(5) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(8)**

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

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 **[**[F60]£2,063**]**; or

(b) in all other cases, a fee of **[**[F61]£8,252**]**.

(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 **[**[F62]£6,504**]**.

(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, **[**[F63]both read with Regulation (EU) No 722/2012**]** 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—

[F64(a) in respect of an initial inspection pursuant to regulation 45(7)(a), a fee of **[**F65£15,904**]** 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 **[**F66£10,160**]**,

(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 **[**F66£10,160**]**, 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 **[**F66£10,160**]**,

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

(c) in respect of an inspection pursuant to regulation 45(7)(b), a fee of **[**F67£4,404**]** plus the amounts specified in paragraph (3A).**]**

[F68(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 **[**F69£361.20**]** 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 **[**F70£90.30**]** 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).**]**

[F71(3C) A UK notified body that applies to the Secretary of State for a renewal of its designation pursuant to article 4 of Regulation (EU) No 920/2013 shall pay to the Secretary of State—

(a) a fee of £8,252 in respect of the application; and

(b) where an audit is carried out in connection with the application, a fee of £15,904 in respect of the audit.

(3D) Where the Secretary of State conducts an assessment of a UK notified body pursuant to article 5 of Regulation (EU) No 920/2013, the UK notified body shall pay to the Secretary of State—

(a) if the assessment relates to the UK notified body's assessment of clinical data only, a fee of £2,586; or

(b) in any other case, a fee of £3,876.

(3E) A UK notified body that submits a summary evaluation report to the Secretary of State pursuant to article 5(4) of Regulation (EU) No 722/2012 shall pay to the Secretary of State a fee of £532.**]**

(4) A fee under this regulation—

(a) in connection with an application for designation under **[**F72regulation 45(1),**]** a variation under regulation 45(4)**[**F73, a renewal under Regulation (EU) No 920/2013 (but not any associated audit) or a submission of a summary evaluation report under Regulation (EU) No 722/2012**]**—

(i) shall be payable when the application **[**F74or submission**]** to the Secretary of State is made, and

(ii) shall accompany the application **[**F75or submission**]** when it is made;

(b) in connection with an inspection pursuant to regulation 45(7) **[**F76or an audit or assessment pursuant to Regulation (EU) No 920/2013**]**, 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.

[F77(5) In this regulation, "Regulation (EU) No 920/2013" means Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices.**]**

Extent Information

E6 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F60 Sum in reg. 54(1)(a) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(2)(a)**

F61 Sum in reg. 54(1)(b) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(2)(b)**

F62 Sum in reg. 54(2) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(3)**

F63 Words in reg. 54(3) substituted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **16**

F64 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)**

F65 Sum in reg. 54(3)(a) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(4)(a)**

F66 Sum in reg. 54(3)(b) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(4)(b)**

F67 Sum in reg. 54(3)(c) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(4)(c)**

F68 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)**

F69 Sum in reg. 54(3A)(a)(i) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(5)(a)**

F70 Sum in reg. 54(3A)(a)(ii) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(5)(b)**

F71 Reg. 54(3C)-(3E) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(6)**
F72 Words in reg. 54(4)(a) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(i)**
F73 Words in reg. 54(4)(a) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(ii)**
F74 Words in reg. 54(4)(a)(i) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(iii)**
F75 Words in reg. 54(4)(a)(ii) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(iii)**
F76 Words in reg. 54(4)(b) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(b)**
F77 Reg. 54(5) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(8)**

Fees payable in connection with the designation etc. of [F29]... conformity assessment bodies E+W+S

55.—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 48 as **[**[F30]a CAB**]** 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 **[**[F31]£2,063**]**; or

(b) in all other cases, a fee of **[**[F32]£8,252**]**.

(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 48(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 **[**[F33]£6,504**]**.

(3) **[**[F34]Subject to paragraphs (3A) to (3C)**]** where, pursuant to regulation 48(7) the Secretary of State inspects premises for the purposes of deciding whether or not a body is capable of fulfilling the functions of **[**[F35]a CAB**]** arising out of **[**[F36]a mutual recognition agreement**]** which it needs to be able to fulfil, the body shall pay to the Secretary of State—

[[F37](a) in respect of an initial inspection pursuant to regulation 48(7)(a), other than an inspection referred to in sub-paragraph (c), fee of **[**[F38]£15,904**]** plus the amounts specified in paragraph (3D);

(b) in respect of any other inspection pursuant to regulation 48(7)(a), other than an inspection referred to in sub-paragraph (c), a fee of **[**[F39]£4,404**]** plus the amounts specified in paragraph (3D);

(c) in respect of an inspection pursuant to regulation 48(7)(a) conducted on the same date and at the same premises as an inspection pursuant to regulation 45(7), a fee of **[**[F40]£1,880**]**;

(d) in respect of an inspection pursuant to regulation 48(7)(b), a fee of **[**[F41]£4,404**]** plus the amounts specified in paragraph (3D).**]**

[[F42](3A) Where the Secretary of State conducts two or more inspections pursuant to regulation 48(7)(a) on the same date and at the same premises, other than inspections referred to in paragraph (3)(c), and one of the inspections is an initial inspection, the fee payable shall be **[**[F43]£15,904**]** plus—

(a) **[**[F44]£1,880**]** for each additional inspection; and

(b) the amounts specified in paragraph (3D).

(3B) Where the Secretary of State conducts two or more inspections pursuant to regulation 48(7)(a) on the same date and at the same premises, other than inspections referred to in paragraph (3)(c), and none of the inspections is an initial inspection, the fee payable shall be **[**[F45]£4,404**]** plus—

(a) **[**[F46]£1,880**]** for each additional inspection; and

(b) the amounts specified in paragraph (3D)

(3C) Where the Secretary of State conducts two or more inspections referred to in paragraph (3)(c) on the same date and at the same premises, the fee payable for the inspections pursuant to regulation 48(7)(a) shall be **[**[F47]£1,880**]** for each inspection.

(3D) The additional amounts payable in respect of an inspection referred to in paragraphs (3) to (3B) 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 **[**[F48]£361.20**]** 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 **[**[F49]£90.30**]** per hour;

(b) the actual costs of travel, accommodation and subsistence, and

(c) out of pocket expenses.**]**

(4) A fee under this regulation—

(a) in connection with an application for designation under regulation 48(1) or a variation under regulation 48(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 48(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.

Extent Information

E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F29 Word in reg. 55 heading omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(4)(a)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 7** and S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**

F30 Words in reg. 55(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(4)(b)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 7** and S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**

F31 Sum in reg. 55(1)(a) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(2)(a)**

F32 Sum in reg. 55(1)(b) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(2)(b)**

F33 Sum in reg. 55(2) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(3)**

F34 Words in reg. 55(3) 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(3)(c)(i)**

F35 Words in reg. 55(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(4)(c)(i)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 7** and S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**

F36 Words in reg. 55(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(4)(c)(Ii)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 7** and S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**

F37 Reg. 55(3)(a)-(d) substituted for reg. 55(3)(a)-(c) (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(3)(c)(ii)**

F38 Sum in reg. 55(3)(a) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(4)(a)**

F39 Sum in reg. 55(3)(b) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(4)(b)**

F40 Sum in reg. 55(3)(c) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(c)(iii)**

F41 Sum in reg. 55(3)(d) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(4)(c)**

F42 Reg. 55(3A)-(3D) 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(3)(d)**

F43 Sum in reg. 55(3A) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(5)**

F44 Sums in reg. 55(3A) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(d)**

F45 Sum in reg. 55(3B) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(6)**

F46 Sums in reg. 55(3B) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(e)**

F47 Sum in reg. 55(3C) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(f)**

F48 Sum in reg. 55(3D)(a)(i) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(7)(a)**

F49 Sum in reg. 55(3D)(a)(ii) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(7)(b)**

Fees payable in connection with the designation etc. of [F78]... conformity assessment bodies N.I.

55.—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 48 as **[**[F79]a CAB**]** 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 **[**[F80]£2,063**]**; or

(b) in all other cases, a fee of **[**[F81]£8,252**]**.

(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 48(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 **[**[F82]£6,504**]**.

(3) **[**[F83]Subject to paragraphs (3A) to (3C)**]** where, pursuant to regulation 48(7) the Secretary of State inspects premises for the purposes of deciding whether or not a body is capable of fulfilling the functions of **[**[F84]a CAB**]** arising out of **[**[F85]a UK mutual recognition agreement**]** which it needs to be able to fulfil, the body shall pay to the Secretary of State—

[F86(a) in respect of an initial inspection pursuant to regulation 48(7)(a), other than an inspection referred to in sub-paragraph (c), fee of **[**F87£15,904**]** plus the amounts specified in paragraph (3D);

(b) in respect of any other inspection pursuant to regulation 48(7)(a), other than an inspection referred to in sub-paragraph (c), a fee of **[**F88£4,404**]** plus the amounts specified in paragraph (3D);

(c) in respect of an inspection pursuant to regulation 48(7)(a) conducted on the same date and at the same premises as an inspection pursuant to regulation 45(7), a fee of **[**F89£1,880**]**;

(d) in respect of an inspection pursuant to regulation 48(7)(b), a fee of **[**F90£4,404**]** plus the amounts specified in paragraph (3D).**]**

[F91(3A) Where the Secretary of State conducts two or more inspections pursuant to regulation 48(7)(a) on the same date and at the same premises, other than inspections referred to in paragraph (3)(c), and one of the inspections is an initial inspection, the fee payable shall be **[**F92£15,904**]** plus—

(a) **[**F93£1,880**]** for each additional inspection; and

(b) the amounts specified in paragraph (3D).

(3B) Where the Secretary of State conducts two or more inspections pursuant to regulation 48(7)(a) on the same date and at the same premises, other than inspections referred to in paragraph (3)(c), and none of the inspections is an initial inspection, the fee payable shall be **[**F94£4,404**]** plus—

(a) **[**F95£1,880**]** for each additional inspection; and

(b) the amounts specified in paragraph (3D)

(3C) Where the Secretary of State conducts two or more inspections referred to in paragraph (3)(c) on the same date and at the same premises, the fee payable for the inspections pursuant to regulation 48(7)(a) shall be **[**F96£1,880**]** for each inspection.

(3D) The additional amounts payable in respect of an inspection referred to in paragraphs (3) to (3B) 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 **[**F97£361.20**]** 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 **[**F98£90.30**]** per hour;

(b) the actual costs of travel, accommodation and subsistence, and

(c) out of pocket expenses.**]**

(4) A fee under this regulation—

(a) in connection with an application for designation under regulation 48(1) or a variation under regulation 48(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 48(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.

Extent Information

E7 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F78 Word in reg. 55 heading omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 21(a)**

F79 Words in reg. 55(1) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 21(b)**

F80 Sum in reg. 55(1)(a) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(2)(a)**

F81 Sum in reg. 55(1)(b) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(2)(b)**

F82 Sum in reg. 55(2) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(3)**

F83 Words in reg. 55(3) 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(3)(c)(i)**

F84 Words in reg. 55(3) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 21(c)(i)**

F85 Words in reg. 55(3) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 21(c)(ii)**

F86 Reg. 55(3)(a)-(d) substituted for reg. 55(3)(a)-(c) (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(3)(c)(ii)**

F87 Sum in reg. 55(3)(a) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(4)(a)**

F88 Sum in reg. 55(3)(b) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(4)(b)**

F89 Sum in reg. 55(3)(c) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(c)(iii)**

F90 Sum in reg. 55(3)(d) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(4)(c)**

F91 Reg. 55(3A)-(3D) 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(3)(d)**

F92 Sum in reg. 55(3A) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(5)**

F93 Sums in reg. 55(3A) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(d)**

F94 Sum in reg. 55(3B) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(6)**

F95 Sums in reg. 55(3B) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(e)**

F96 Sum in reg. 55(3C) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(f)**

F97 Sum in reg. 55(3D)(a)(i) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(7)(a)**

F98 Sum in reg. 55(3D)(a)(ii) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **4(7)(b)**

Fees payable in relation to clinical investigation notices E+W+S

56.—(1) Subject to paragraph (2), any person required to give the Secretary of State notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) shall, in respect of the consideration by the Secretary of State of the information that the person is required to submit, pay to the Secretary of State—

(a) if, as regards that device, it is the second or subsequent occasion on which the person has given the Secretary of State notice of an intended clinical investigation, and the changes from the immediately preceding notice are limited to addressing the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation—

(i) a fee, if the device is a Group A device, of **[**F50£2,920**]**, or

(ii) a fee, if the device is a Group B device, of **[**F50£3,570**]**; or

(b) in all other cases—

(i) a fee, if the device is a Group A device, of **[**F51£3,820**]**, or

(ii) a fee, if the device is a Group B device, of **[**F51£5,040**]**.

(2) Except where paragraph (3) **[**F52or (3A)**]** applies, no fee shall be payable in respect of a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) where the manufacturer or **[**F53their UK responsible person**]** has previously given such notice in relation to that device.

(3) A fee shall be payable where the investigational plan which forms part of the statement accompanying the notice differs from the plan submitted with the immediately preceding notice in that it includes—

(a) a change to address the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation;

(b) a change to the number of patients or devices forming the basis of the proposed trial;

(c) a change or extension in the indications for use of the device or to the purpose or objectives of the trial;

(d) a change in any of the materials used in the device that come into direct contact with the human body if the new materials are not known to be biocompatible; or

(e) a change in the design of the device involving a novel feature not previously tested, being a change that has a direct effect on a vital physiological function.

[F54(3A) Any person who submits an amendment to a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) shall pay to the Secretary of State—

(a) a fee, if the device is a Group A device, of £207; or

(b) a fee, if the device is a Group B device, of £331.**]**

(4) A fee under this regulation—

(a) shall be payable when the notice to which it relates is given to the Secretary of State; and

(b) shall accompany that notice when it is given.

Extent Information

E4 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F50 Sums in reg. 56(1)(a) substituted (1.4.2013) by The Medical Devices (Fees Amendment) Regulations 2013 (S.I. 2013/525), regs. 1, **2(2)(a)**

F51 Sums in reg. 56(1)(b) substituted (1.4.2013) by The Medical Devices (Fees Amendment) Regulations 2013 (S.I. 2013/525), regs. 1, **2(2)(b)**

F52 Words in reg. 56(2) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **5(2)**

F53 Words in reg. 56(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(4A)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **49**); 2020 c. 1, **Sch. 5 para. 1(1)**

F54 Reg. 56(3A) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **5(3)**

Fees payable in relation to clinical investigation notices N.I.

56.—(1) Subject to paragraph (2), any person required to give the Secretary of State notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) shall, in respect of the consideration by the Secretary of State of the information that the person is required to submit, pay to the Secretary of State—

(a) if, as regards that device, it is the second or subsequent occasion on which the person has given the Secretary of State notice of an intended clinical investigation, and the changes from the immediately preceding notice are limited to addressing the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation—

(i) a fee, if the device is a Group A device, of **[**F99£2,920**]**, or

(ii) a fee, if the device is a Group B device, of **[**F99£3,570**]**; or

(b) in all other cases—

(i) a fee, if the device is a Group A device, of **[**F100£3,820**]**, or

(ii) a fee, if the device is a Group B device, of **[**F100£5,040**]**.

(2) Except where paragraph (3) **[**F101or (3A)**]** applies, no fee shall be payable in respect of a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) where the manufacturer or his authorised representative has previously given such notice in relation to that device.

(3) A fee shall be payable where the investigational plan which forms part of the statement accompanying the notice differs from the plan submitted with the immediately preceding notice in that it includes—

(a) a change to address the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation;

(b) a change to the number of patients or devices forming the basis of the proposed trial;

(c) a change or extension in the indications for use of the device or to the purpose or objectives of the trial;

(d) a change in any of the materials used in the device that come into direct contact with the human body if the new materials are not known to be biocompatible; or

(e) a change in the design of the device involving a novel feature not previously tested, being a change that has a direct effect on a vital physiological function.

[[F102](3A) Any person who submits an amendment to a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) shall pay to the Secretary of State—

(a) a fee, if the device is a Group A device, of £207; or

(b) a fee, if the device is a Group B device, of £331.**]**

(4) A fee under this regulation—

(a) shall be payable when the notice to which it relates is given to the Secretary of State; and

(b) shall accompany that notice when it is given.

Extent Information

E8 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F99 Sums in reg. 56(1)(a) substituted (1.4.2013) by The Medical Devices (Fees Amendment) Regulations 2013 (S.I. 2013/525), regs. 1, **2(2)(a)**

F100 Sums in reg. 56(1)(b) substituted (1.4.2013) by The Medical Devices (Fees Amendment) Regulations 2013 (S.I. 2013/525), regs. 1, **2(2)(b)**

F101 Words in reg. 56(2) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **5(2)**

F102 Reg. 56(3A) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **5(3)**

[[F55]Fees in connection with approval of coronavirus test devices

56A.—(1) A person who makes an application to the Secretary of State under regulation 38A(1) must pay to the Secretary of State a fee of—

(a) £14,000; or

(b) if the person is a small or medium-sized enterprise, £6,200.

(2) Where the Secretary of State, in accordance with regulation 38A(4), treats an application made before the coming into force of regulation 38A as an application made under that regulation, a payment made in respect of that application before the coming into force of this regulation must be treated as—

(a) a payment meeting the requirements of paragraph (1), if that payment would have met those requirements after their coming into force; or

(b) a payment contributing in part to the payment required by paragraph (1), if that payment would not have met those requirements after their coming into force.

(3) In this regulation—

(a) a person is a small or medium-sized enterprise if it and persons associated with it employ no more than 250 individuals in total; and

(b) "persons associated with it" has the same meaning as in section 882 of the Corporation Tax Act 2010.**]**

Textual Amendments

F55 Reg. 56A inserted (28.7.2021) by The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 (S.I. 2021/910), regs. 1(1), **9**

Unpaid fees

57. All unpaid sums due by way of, or on account of, any fees payable under this Part are recoverable as debts due to the Crown.

Waivers, reductions and refunds E+W+S

58.—(1) The Secretary of State may—

(a) waive payment of any fee or reduce any fee or part of a fee otherwise payable under this Part;

(b) refund the whole or part of any fee paid pursuant to this Part.

(2) Without prejudice to the generality of paragraph (1), where—

(a) a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) is withdrawn within the period of 7 days beginning with the date of its receipt by the Secretary of State; or

(b) an application for designation as—

(i) **[**F56an approved body**]** under regulation 45(1), or

(ii) **[**F57a CAB**]** under regulation 48(1),

(other than one submitted only to address the grounds of rejection of a previous application) is withdrawn within the period of 21 days beginning with the date of its receipt by the Secretary of State,

the fee payable shall be reduced to fifty per cent of the fee otherwise payable in respect of such notice or application, and any excess already paid shall be refunded.

Textual Amendments

F56 Words in reg. 58(2)(b)(i) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(5)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **50**); 2020 c. 1, **Sch. 5 para. 1(1)**

F57 Words in reg. 58(2)(b)(ii) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(5)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **50**); 2020 c. 1, **Sch. 5 para. 1(1)**

Waivers, reductions and refunds N.I.

58.—(1) The Secretary of State may—

(a) waive payment of any fee or reduce any fee or part of a fee otherwise payable under this Part;

(b) refund the whole or part of any fee paid pursuant to this Part.

(2) Without prejudice to the generality of paragraph (1), where—

(a) a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) is withdrawn within the period of 7 days beginning with the date of its receipt by the Secretary of State; or

(b) an application for designation as—

(i) a notified body under regulation 45(1), or

(ii) **[**[F103]a CAB**]** under regulation 48(1),

(other than one submitted only to address the grounds of rejection of a previous application) is withdrawn within the period of 21 days beginning with the date of its receipt by the Secretary of State,

the fee payable shall be reduced to fifty per cent of the fee otherwise payable in respect of such notice or application, and any excess already paid shall be refunded.

Textual Amendments

F103 Words in reg. 58(2)(b)(ii) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 22**

Status:
Point in time view as at 28/07/2021.

Changes to legislation:
The Medical Devices Regulations 2002, PART VI is up to date with all changes known to be in force on or before 31 May 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.