STATUTORY INSTRUMENTS

1995 No. 2487

FEES AND CHARGES

The Medical Devices Fees Regulations 1995

Made - - - -	*20th September 1995*
Laid before Parliament	*25th September 1995*
Coming into force - -	*17th October 1995*

The Secretary of State, with the consent of the Treasury, in exercise of the powers conferred on him by section 56(1) and (2) of the Finance Act 1973(**1**) and of all other powers enabling him in that behalf, hereby makes the following Regulations:—

Citation and Commencement

1. These Regulations may be cited as the Medical Devices Fees Regulations 1995 and shall come into force on 17th October 1995.

Interpretation

2. In these Regulations, unless the context otherwise requires—

(a) "the 1990 Directive" means Council Directive 90/385/EEC on the approximation of the laws of Member States relating to active implantable medical devices(**2**) as amended by the 1993 Directive and by Council Directive 93/68/EEC(**3**);

"the 1992 Regulations" means the Active Implantable Medical Devices Regulations 1992(**4**);

"the 1993 Directive" means Council Directive 93/42/EEC concerning medical devices(**5**);

"the 1994 Regulations" means the Medical Devices Regulations 1994(**6**);

"active implantable device" means a device as defined in the 1992 Regulations;

(**1**) 1973 c. 51.
(**2**) OJ No. L189, 20.7.90, p. 17; implemented by S.I.1992/3146, amended by S.I. 1995/1671
(**3**) OJ No. L 220, 30.8.93, p. 1.
(**4**) S.I. 1992/3146; amended by S.I. 1995/1671
(**5**) OJ No. L169, 12.7.93, p. 1; implemented by S.I. 1994/3017.
(**6**) S.I. 1994/3017.

"application for designation" means an application for designation as a notified body under regulation 8(1) of the 1992 Regulations or regulation 17(1) of the 1994 Regulations;

"device" means a device as defined in the 1994 Regulations;

"Group A device" means a Class I device, a Class IIa device or a Class IIb device other than an implantable or long term invasive device;

"Group B device" means a Class IIb implantable or long term invasive device, a Class III device or an active implantable device;

"half day" means a period of three and a half hours;

"material extension" means an extension—

(a) to add or substitute tasks relating to:

(i) active implantable devices in addition to or in substitution of tasks relating to other devices, or

(ii) devices which are materially different in technology from devices in connection with which they have already been designated tasks having regard to the risk they pose to the health and safety of patients and the skills needed to assess those risks,

(b) to add or substitute tasks relating to the procedures specified in Annex 3 or 4 of the 1990 Directive or Annex III or IV of the 1993 Directive in addition to or in substitution of tasks relating to procedures specified in Annex 2 or 5 of the 1990 Directive or Annex II, V or VI of the 1993 Directive or vice versa,

(c) to add or substitute tasks in relation to the procedures specified in Annex 3 of the 1990 Directive or Annex III of the 1993 Directive in addition to or in substitution of tasks relating to the procedures specified in Annex 4 of the 1990 Directive or Annex IV of the 1993 Directive,

(d) to add or substitute tasks relating to the procedures specified in Annex 2 of the 1990 Directive or Annex II of the 1993 Directive in addition to or in substitution of tasks relating to the procedures specified in Annex 5 of the 1990 Directive or Annex V or VI of the 1993 Directive, or

(e) to add or substitute tasks relating to the procedures specified in Annex V of the 1993 Directive in addition to or in substitution of tasks specified in Annex VI of the 1993 Directive;

"notice" means notice to the Secretary of State under regulation 7(1) of the 1992 Regulations or regulation 16(1) of the 1994 Regulations of the making available of a device for clinical investigation;

"the Table" means the table set out in the Schedule to these Regulations;

(b) any other words and expressions used both in these Regulations and in the 1990 Directive or the 1993 Directive shall bear the same meaning in these Regulations as they bear in the relevant Directive;

(c) a device shall be classified as belonging to Class I to III or as implantable or long term invasive in accordance with the criteria in Annex IX of the 1993 Directive;

(d) fee described by reference to a number and letter means a fee provided for in column (3) of the Table in relation to that number and letter in column (1) of the Table.

Fees

3. Subject to the following provisions of these Regulations, the fee payable in connection with the services provided by the Department of Health in pursuance of the Secretary of State's functions under the 1990 Directive and the 1993 Directive shall, in respect of each matter specified in column (2) of the Table be that specified in, or determined in accordance with, the entry relating to it in column (3) of the Table.

Exception

4.—(1) Subject to paragraph (2), no fee shall be payable in connection with services provided in respect of a notice relating to a device where the manufacturer has previously given notice in relation to that device.

(2) A fee shall be payable where the investigation plan forming part of the statement accompanying the notice in accordance with regulation 7(1) of the 1992 Regulations or regulation 16(1)(a) of the 1994 Regulations differs from the plan submitted with the immediately preceding notice in that it includes:—

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

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

(c) 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,

(d) 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.

Time for Payment

5. Fees 1(a) and (b) and 2(a) to (d) shall accompany the respective notice, application for designation or request for extension and any other fee shall be payable within one month of receipt of a written notice given by the Secretary of State requiring payment of the fee.

Withdrawals

6.—(1) Where:—

(a) a notice is withdrawn within the period of 5 days beginning with the date of its receipt by the Secretary of State, or

(b) an application for designation (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 shall be fifty per cent of the fee otherwise payable on such notice or application.

(2) Where a reduced fee becomes payable under paragraph (1), the difference between the amount of that fee and any other fee already paid in respect of the notice or application for designation which is being withdrawn shall be repaid by the Secretary of State.

Stephen Dorrell
One of Her Majesty's Principal Secretaries of State

12th September 1995.

We consent to the making of these Regulations.

David Willetts
Bowen Wells
Two of the Lords Commissioners of Her Majesty's Treasury.

20th September 1995.

SCHEDULE Regulation 3

TABLE OF FEES

Column 1 Fee No.	Column 2 Matter	Column 3 Fee
1(a)	notice in respect of a (i) Group A device (ii) Group B device except where fee 1(b) is payable	(i) £900 (ii) £3,000
1(b)	second or subsequent notice in respect of a device given only to address the grounds for any notice by the Secretary of State under regulation 7(2) of the 1992 Regulations or regulation 16(2) of the 1994 Regulations that the device in question should not be made available for purposes of clinical investigation being a notice in respect of a (i) Group A device (ii) Group B device	(i) £650 (ii) £2,100
2(a)	application for designation except where fee 2(b) is payable	£1,300
2(b)	second or subsequent application for designation made only to address the grounds for rejection of a previous application	£400
2(c)	request by a body for a material extension to be made to the scope of the tasks in respect of which it has applied to be designated	£1,300
2(d)	request by a notified body for a material extension to be made to the scope of the tasks which it is designated by the Secretary of State to carry out	£1,300
2(e)	inspection of premises pursuant to regulation 8(7)(a) of the 1992 Regulations or regulation 17(7)(a) of the 1994 Regulations being an inspection for the purpose	**i)** £2,700 plus— (a) time spent by a member of staff out of the office while undertaking a site visit (to include time spent travelling or staying overnight) at the rate of

Column 1 Fee No.	Column 2 Matter	Column 3 Fee
	of deciding whether or not a body is one in respect of which the conditions specified in Annex 8 of the 1990 Directive or Annex XI of the 1993 Directive (i) are fulfilled as respects the tasks which it is to carry out (ii) continue to be fulfilled as respects the tasks which it carries out	160 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, (b) actual costs of travel, accommodation and subsistence, and (c) out of pocket expenses **ii)** £1,600 plus— (a) time spent by a member of staff out of the office while undertaking a site visit (to include time spent travelling or staying overnight) at the rate of 160 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, (b) actual costs of travel, accommodation and subsistence, and (c) out of pocket expenses
2(f)	inspection of premises pursuant to regulation 8(7)(b) of the 1992 Regulations or regulation 17(7)(b) of the 1994 Regulations	£1,600 plus— time spent by a member of staff out of the office while undertaking a site visit (to include time spent travelling or staying overnight) at the rate of 160 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, actual costs of travel, accommodation and subsistence, and out of pocket expenses

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations ("the Regulations") prescribe the fees payable in connection with the services provided by the Department of Health in pursuance of the Secretary of State's functions under Council Directives 90/385/EEC on the approximation of the laws of member States relating to active implantable medical devices and 93/42/EEC concerning medical devices.

The main provisions are as follows.

Regulation 3 provides that, subject to the provisions of the Regulations, the fee payable in connection with the services provided by the Department of Health are as specified in the Schedule to the Regulations.

Regulation 4 provides, subject to the exception in regulation 4(2), that no fee shall be payable in connection with a notice by a manufacturer of his intention to make a device available for clinical investigation if he has previously given a notice in connection with that device.

Regulation 4(2) provides that a fee shall be payable where the investigation plan accompanying the notice differs from the plan submitted with the immediately preceding notice in any of the ways specified.

Regulation 5 provides that fees 1(a), 1(b) and 2(a) to 2(d) shall accompany the respective notice, application for designation, or request for extension and for any other fee to be payable within one month of the Secretary of State's written request for payment.

Regulation 6 provides for reduced fees to be payable on notices or applications for designation which are withdrawn within a certain period and for the difference between the reduced fee and the fee otherwise payable to be repaid by the Secretary of State.

A compliance cost assessment is available, copies of which have been placed in the libraries of both Houses of Parliament.

Copies of the assessment are also available from the Medical Devices Agency, 11th Floor South, Hannibal House, Elephant and Castle, London SE1 6TQ.