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STATUTORY INSTRUMENTS

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**2012 No. 1501**

**The Quality and Safety of Organs Intended  
for Transplantation Regulations 2012**

**PART 3**

Licensing

**Licensing requirement**

5.—(1) No person shall carry out a procurement activity or a transplantation activity otherwise than under the authority of a licence under Schedule 1.

(2) The authority conferred by a licence extends to the licence holder, any person designated by the licence holder and any person acting under the supervision of either of them.

(3) The Authority shall specify in the licence which procurement activity or transplantation activity a person may undertake under the licence.

(4) The Authority shall permit a person making an application for two or more—

- (a) procurement activities;
- (b) transplantation activities; or
- (c) procurement activities and transplantation activities, to make single application in respect of the activities,

to make a single application in respect of the activities.

(5) Schedule 1 has effect.

[<sup>F1</sup>(6) Schedule 1A (which specifies information to be collected in certain circumstances for the purposes of paragraph 5 of Schedule 1) has effect.]

**F1** [Reg. 5\(6\) inserted \(31.12.2020\) by The Quality and Safety of Organs Intended for Transplantation \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/483\), regs. 1, 3\(4\); 2020 c. 1, Sch. 5 para. 1\(1\)](#)

**Application of the 2004 Act in relation to licences under Schedule 1**

6.—(1) The provisions of the 2004 Act referred to in paragraph (2) shall apply, subject to the modifications specified in [<sup>F2</sup>paragraphs (4) and (5)], in relation to a licence under Schedule 1 to these Regulations as they apply to licences under paragraph 1 of Schedule 3, (licences for the purposes of section 16) to that Act.

(2) The provisions are—

- (a) section 19(1), (2), (5) and (7) (right to reconsideration of licensing decisions);
- (b) sections 20 to 24 (which relate to appeals and powers to give directions);
- (c) section 37(1) to (5) (directions); and

- (d) paragraphs 2(4)(c) to (f) and (5), 5, 7 to 11, and 13 of Schedule 3 (licences for the purposes of section 16).
- (3) In their application by virtue of this regulation, those provisions extend to Scotland (as well as to the rest of the United Kingdom).
- (4) In their application by virtue of this regulation—
- (a) section 19 (right to reconsideration of licensing decisions) shall apply as if in subsection (2) the words “, or designated individual,” were omitted <sup>F3</sup>...;
- (b) section 23 (conduct of licensed activities) shall apply as if subsection (1) were limited to directions that the Authority considers necessary to ensure compliance with [<sup>F4</sup>these Regulations, as they apply in relation to Great Britain, and with the Directive and the Implementing Directive, as they apply in relation to Northern Ireland];
- (c) section 24 (changes of licence circumstance) shall apply as if subsection (1) were limited to directions that the Authority considers necessary to ensure compliance with [<sup>F4</sup>these Regulations, as they apply in relation to Great Britain, and with the Directive and the Implementing Directive, as they apply in relation to Northern Ireland] and as if for subsections (2)(b) and (3)(b) there were substituted—
- “(b) on any other person who has authority to act under the licence.”;
- (d) section 37 (directions) shall apply—
- (i) as if the reference in subsection (1) to “this Part” were to these Regulations; and
- (ii) as if any reference in subsection (5) to a licence were to a licence under Schedule 1 to these Regulations;
- (e) paragraph 2(4)(c) to (f) and 5 (characteristics of licence) of Schedule 3 shall apply as if it were limited to directions that the Authority considers necessary to ensure compliance with [<sup>F4</sup>these Regulations, as they apply in relation to Great Britain, and with the Directive and the Implementing Directive, as they apply in relation to Northern Ireland];
- (f) paragraph 7 (power to revoke licence) of that Schedule shall apply as if sub-paragraphs (1)(b) and (2)(b), (e) and (f) were omitted and as if for sub-paragraph (2)(b) there were substituted—
- “(b) if it is satisfied that the licence holder has failed to discharge, or is unable because of incapacity to discharge, any of its duties.”;
- (g) paragraph 8 (power to vary licence) of that Schedule shall apply as if sub-paragraphs (1), (2)(b), (3) and (4) were omitted;
- (h) paragraph 9 (power to suspend licence) of that Schedule shall apply as if for sub-paragraph (3) there were substituted the following sub-paragraph—
- “(3) Notice under sub-paragraph (1) shall be given to the licence holder or to any other person who has authority to act under the licence.”;
- (i) paragraph 10 (procedure in relation to licensing decisions) of that Schedule shall apply as if sub-paragraph (2)(b) were omitted; and
- (j) paragraph 11 (notification of licensing decisions) of that Schedule shall apply as if sub-paragraphs (1)(b) and (3)(b) were omitted and as if for sub-paragraphs (2)(b) and 4(b) there were substituted—
- “(b) any other person who has authority to act under the licence.”;
- (5) In its application by virtue of this regulation, section 22 (appeal on a point of law) of the 2004 Act is to have effect in Scotland as if the reference to the High Court were a reference to the Court of Session.

- F2** Words in reg. 6(1) substituted (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4(a)**
- F3** Words in reg. 6(4)(a) omitted (14.7.2014) by virtue of [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4(b)**
- F4** Words in [reg. 6](#) substituted (31.12.2020) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/483\)](#), regs. 1, **3(5)** (as substituted by S.I. 2020/1305, regs. 1, **6**); 2020 c. 1, **Sch. 5 para. 1(1)**

### **Extension of other provisions of the 2004 Act to Scotland**

7.—(1) The following provisions shall extend to Scotland (as well as to the rest of the United Kingdom), so far as they relate to activities within section 14(1)(i) of the 2004 Act—

- (a) section 14 (remit of the Human Tissue Authority); and
- (b) section 15(a), (b), (d), (e) and (f) (general functions), subject to the modifications in paragraph (2).

(2) In its application by virtue of paragraph (1) section 15(e) and (f) of the 2004 Act is to be read as including a reference to advising the Scottish Ministers.

### **Breach of requirement to hold a licence**

8.—(1) A person who contravenes regulation 5(1) commits an offence unless that person reasonably believes that—

- (a) the activity being undertaken is not an activity to which regulation 5(1) applies; or
- (b) they are acting under the authority of a licence under Schedule 1.

(2) A person guilty of an offence under paragraph (1) shall be liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment—
  - (i) to imprisonment for a term not exceeding 2 years,
  - (ii) to a fine, or
  - (iii) to both.

### **Preconditions to grant of a licence**

9.—(1) The Authority may not grant a licence under Schedule 1 unless the following requirements are met.

(2) The Authority must be satisfied that the applicant—

- (a) meets the relevant conditions in Schedule 1 and will continue to do so; and
- (b) meets any other conditions or requirements that the Authority has imposed.

(3) A copy of the conditions to be imposed by the licence must have been shown to, and acknowledged in writing by, the applicant for the licence.

### **Duty of the licence holder**

10. It shall be the duty of the licence holder to secure compliance with—

- (a) the conditions of the licence granted by the Authority to the licence holder under paragraph 1 of Schedule 1; and

- (b) any requirements imposed by directions given under section 23(1) (conduct of licensed activities) or 24(1) (changes of licence circumstance) of, or paragraph 2(4)(c) to (f) (characteristics of licence) of Schedule 3 to, the 2004 Act, as applied by regulation 6.

### Directions

**11.**—(1) The Authority shall give directions to a licence holder under section 23(1) (conduct of licensed activities) of the 2004 Act, as applied by regulation 6, in accordance with Schedule 2.

(2) The Authority shall revise directions given by virtue of paragraph (1) as it considers necessary.

(3) Schedule 2 has effect.

### Guidance

**12.**—(1) The Authority shall publish such guidance to licence holders as it considers necessary to ensure compliance with [<sup>F5</sup>these Regulations, as they apply in relation to Great Britain, and with the Directive and the Implementing Directive, as they apply in relation to Northern Ireland] .

(2) The Authority shall keep the guidance published under paragraph (1) under review and prepare revised guidance when it considers it necessary to do so.

(3) The Authority shall publish the guidance under this regulation in such a way as, in its opinion, is likely to bring it to the attention of licence holders.

**F5** Words in [reg. 12\(1\)](#) substituted (31.12.2020) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/483\)](#), regs. 1, [3\(6\)](#) (as substituted by [S.I. 2020/1305](#), regs. 1, 7); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**Changes to legislation:**

There are currently no known outstanding effects for the The Quality and Safety of Organs Intended for Transplantation Regulations 2012, PART 3.