
STATUTORY INSTRUMENTS

2007 No. 1523

**The Human Tissue (Quality and Safety
for Human Application) Regulations 2007**

PART 2

**LICENSING OF ACTIVITIES RELATING TO THE
USE OF TISSUE FOR HUMAN APPLICATION**

Licensing requirement

7.—(1) No person shall store tissue or cells intended for human application otherwise than under the authority of a licence under Schedule 1.

(2) Subject to paragraphs (4) and (6), no person shall do an activity to which this paragraph applies otherwise than—

- (a) under the authority of a licence under Schedule 1, or
- (b) in pursuance of a third party agreement.

(3) Paragraph (2) applies to the procurement, testing, processing, distribution, import or export of tissue and cells intended for human application.

(4) The Authority may authorise any person to distribute, import or export tissue or cells directly from where the procurement takes place to an organisation responsible for human application for immediate human application.

(5) The Authority may not authorise distribution, import or export under paragraph (4) unless—

- (a) the authorisation relates to tissue or cells specified for the purposes of Article 6(5) of the first Directive, and
- (b) the Authority is satisfied—
 - (i) that the distribution, import or export is necessary for clinical reasons, and
 - (ii) that the case is one of emergency.

(6) Paragraph (2) shall not apply to the distribution to or from, or to the import from or the export to, tissue establishments which are accredited, designated, authorised or licensed under the laws or other measures adopted in an EEA state other than the United Kingdom or in Gibraltar for the purpose of implementing the first, second and third Directives.

(7) Schedule 1 shall apply in relation to licences for the purposes of this regulation.

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

8.—(1) The provisions of the 2004 Act mentioned in paragraph (2) shall apply, subject to the modifications specified in paragraphs (4) to (7), in relation to a licence under Schedule 1 as they apply in relation to licences under paragraph 1 of Schedule 3 (licences for the purposes of section 16) to that Act.

(2) The provisions mentioned in paragraph (1) are—

- (a) section 17 (persons to whom licence applies),
- (b) section 19(1), (2), (5) and (7) (right to reconsideration of licensing decisions),
- (c) sections 20 to 24 (which relate to appeals and powers to give directions),
- (d) section 37(1) to (5) (directions), and
- (e) 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 its application by virtue of paragraph (2)(c), section 22 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.

(5) In its application by virtue of paragraph (2)(d), section 37(1) and (5) of the 2004 Act shall be read—

- (a) as if the reference in subsection (1) to Part 2 of the 2004 Act were to these Regulations, and
- (b) as if any reference in subsection (5) to a licence were to a licence under Schedule 1 to these Regulations.

(6) In their application by virtue of paragraph (2)(e), paragraphs 7(2)(b) and 9(3) of Schedule 3 to the 2004 Act shall be read as if the reference to section 18 of that Act were to regulation 12 of these Regulations.

(7) In its application by virtue of paragraph (2)(e), paragraph 7(2)(c) of Schedule 3 to the 2004 Act is to be read as including a reference to any relevant third party premises in relation to the licence and to the activity carried on on such premises in connection with the licensed activity.

Extension of other provisions of the 2004 Act to Scotland

9.—(1) Section 15(a), (b), (c)(ii), (d), (e) and (f) (general functions) and section 26(1) and (4) to (8) (preparation of codes) of the 2004 Act shall extend to Scotland (as well as to the rest of the United Kingdom), subject to the modifications specified in paragraph (2), so far as those provisions relate to activities within section 14(1)(h) of that Act.

(2) In its application by virtue of paragraph (1)—

- (a) section 15(e) and (f) of the 2004 Act is to be read as including a reference to the Scottish Ministers;
- (b) section 26(5) of the 2004 Act is to be read as including a duty to consult the Scottish Ministers if the code of practice relates to Scotland; and
- (c) section 26(8) of the 2004 Act is to be read as including a reference to Scotland.

Breach of requirement to hold a licence or to act under a third party agreement

10.—(1) A person who contravenes regulation 7(1) commits an offence unless he reasonably believes—

- (a) that what he does is not an activity to which regulation 7(1) applies; or
- (b) that he acts under the authority of a licence under Schedule 1.

(2) A person who contravenes regulation 7(2) commits an offence unless he reasonably believes—

- (a) that what he does is not an activity to which regulation 7(2) applies; or
- (b) that he acts—
 - (i) under the authority of a licence under Schedule 1,

- (ii) in pursuance of a third party agreement, or
 - (iii) in pursuance of an authorisation under regulation 7(4).
- (3) A person guilty of an offence under paragraph (1) or (2) shall be liable—
 - (a) on summary conviction to a fine not exceeding the statutory maximum;
 - (b) on conviction on indictment—
 - (i) to imprisonment for a term not exceeding 2 years, or
 - (ii) to a fine, or
 - (iii) to both.

Preconditions to grant of licence

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

- (2) The proposed designated individual must—
 - (a) be the applicant for the licence, or
 - (b) consent to the application for the licence.
- (3) The Authority must be satisfied that the proposed designated individual—
 - (a) is a suitable person to supervise the activity to be authorised by the licence,
 - (b) will perform the duty imposed by regulation 12,
 - (c) either—
 - (i) has a diploma, certificate or other evidence of formal qualification in the fields of medical or biological sciences awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent, or
 - (ii) is otherwise considered by the Authority to be suitably qualified on the basis of academic qualifications and practical experience, and
 - (d) has at least two years' practical experience which is directly relevant to the activity to be authorised by the licence.
- (4) Where the applicant for the licence is not the proposed designated individual, the Authority must be satisfied that the applicant is a suitable person to be the holder of the licence.
- (5) The Authority must be satisfied that—
 - (a) any premises in respect of which the licence is to be granted, and
 - (b) any premises which are proposed to be relevant third party premises in relation to the licence to be granted,are suitable for the activity to be authorised by the licence.
- (6) A copy of the conditions to be imposed by the licence must have been shown to, and acknowledged in writing by—
 - (a) the applicant for the licence, and
 - (b) where different, the proposed designated individual.
- (7) In this regulation, references to the proposed designated individual are to the individual whom the application proposes that the licence should designate as the person under whose supervision the activity to be authorised by the licence is to be carried on.

Duty of designated individual

12. It shall be the duty of the designated individual to secure—
- (a) that the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity,
 - (b) that suitable practices are used in the course of carrying on that activity, and
 - (c) that—
 - (i) the conditions of the licence,
 - (ii) the conditions of third party agreements, in relation to the licensed activities authorised to be carried on under his supervision, and
 - (iii) the requirements of regulation 13(1),
 are complied with.

Information and confidentiality

13.—(1) It shall be a condition of every licence under Schedule 1 that all necessary arrangements are made to ensure that all information which is collected in pursuance of the licence or a third party agreement in relation to the licence—

- (a) is available for the purpose of tracing donations;
- (b) is kept up-to-date and corrected without delay where any discrepancy relating to such information is identified; and
- (c) is held securely and subject to safeguards against unauthorised additions, deletions, modifications or transfer of information.

(2) Any information which is collected in pursuance of a licence under Schedule 1 or a third party agreement, and from which a donor (living or deceased) or recipient of tissue or cells may be identified, shall not be disclosed except where such disclosure—

- (a) is of information which has been rendered anonymous so that neither the donor nor recipient is identifiable,
- (b) is made in accordance with an order of a court,
- (c) is otherwise required by law,
- (d) is made to a person as a member or employee of the Authority,
- (e) is made to a person who is otherwise acting on behalf of the Authority in the exercise of its functions under these Regulations, including in particular its functions under Part 5 of these Regulations,
- (f) is made to a tissue establishment for the purpose of tracing a donation from donor to recipient or recipient to donor,
- (g) is made to a licence holder or a person to whom a licence applies for the purposes of his functions under the licence,
- (h) is made to a third party in relation to a licence for the purposes of his functions under a third party agreement,
- (i) is made pursuant to any consent to disclosure given by the person, being the donor or recipient of the tissue or cells, whose identity would be disclosed,
- (j) is necessary—
 - (i) for any purpose preliminary to proceedings,
 - (ii) for the purpose of, or in connection with, any proceedings,

- (iii) for the purpose of reporting a suspected offence,
 - (iv) for the purpose of cooperating with a police investigation,
 - (v) for the purpose of investigating a serious adverse event or serious adverse reaction,
 - (k) is made by a licence holder or designated individual in accordance with directions given to that person by the Authority under section 23(1) or 24(1) of, or paragraph 2(4) of Schedule 3 to, the 2004 Act, as applied by regulation 8, or
 - (l) is of information which has been lawfully made available to the public before the disclosure is made.
- (3) References to proceedings in paragraph (2)(j) include any formal procedure for dealing with a complaint.
- (4) Where a disclosure is made to a person pursuant to paragraph (2)(d) or (e), that person shall not further disclose the information received unless the disclosure—
- (a) is made in accordance with paragraph (2), or
 - (b) is made by the Authority for the purpose of its obligations under regulations 17 and 20.

Breach of confidentiality requirement

14.—(1) Any person who discloses any information in breach of regulation 13(2) or (4) shall be guilty of an offence.

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

(a) on summary conviction—

- (i) to a fine not exceeding the statutory maximum, or
- (ii) to imprisonment for a term not exceeding three months, or
- (iii) to both;

(b) on conviction on indictment—

- (i) to a fine, or
- (ii) to imprisonment for a term not exceeding two years, or
- (iii) to both.

(3) In any proceedings for an offence under paragraph (1), it shall be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid commission of the offence.