

Status: Point in time view as at 06/03/2018.

Changes to legislation: Human Tissue Act 2004, SCHEDULE 3 is up to date with all changes known to be in force on or before 08 July 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)

SCHEDULES

SCHEDULE 3

Section 16

LICENCES FOR THE PURPOSES OF SECTION 16

Power to grant licence

1 The Authority may on application grant a licence for the purposes of section 16.

Commencement Information

- I1** Sch. 3 para. 1 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
- I2** Sch. 3 para. 1 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)
- I3** Sch. 3 para. 1 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)
- I4** Sch. 3 para. 1 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, Sch. (with art. 4)
- I5** Sch. 3 para. 1 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, art. 3(2) (with arts. 4, 7, 8)

Characteristics of licence

- 2 (1) A licence shall not authorise the carrying-on of more than one activity to which section 16 applies.
- (2) A licence shall—
- (a) specify the premises where the licensed activity is authorised to be carried on, and
 - (b) designate an individual as the person under whose supervision the licensed activity is authorised to be carried on.
- (3) A licence shall not authorise the licensed activity to be carried on—
- (a) on premises at different places, or
 - (b) under the supervision of more than one individual.
- (4) It shall be a condition of a licence—
- (a) that the licensed activity shall be carried on only on the premises specified in the licence;
 - (b) that the licensed activity shall be carried on only under the supervision of the individual designated in the licence as the person under whose supervision it is authorised to be carried on;
 - (c) that such information about such matters relating to the carrying-on of the licensed activity as may be specified in directions shall be recorded in such form as may be so specified;
 - (d) that any record made for the purposes of the condition in paragraph (c) shall be kept until the end of such period as may be specified in directions;

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- (e) that there shall be provided to such person and at such intervals as may be specified in directions—
 - (i) such copies of, or extracts from, any record to which the condition in paragraph (d) relates, and
 - (ii) such other information,
 as may be so specified;
 - (f) that there shall be paid to the Authority at such times as may be specified in directions sums of such amount as may be so specified in respect of its costs in connection with superintending compliance with the terms of licences.
- (5) Directions for the purposes of sub-paragraph (4) may be given in relation to licences generally, licences of a particular description or a particular licence.

Modifications etc. (not altering text)

- C1** Sch. 3 para. 2(4)(c)-(f) applied (with modifications) (25.5.2007 for specified purposes, 5.7.2007 in so far as not already in force) by [Human Tissue \(Quality and Safety for Human Application\) Regulations 2007 \(S.I. 2007/1523\)](#), reg. 1(2)(3)**8(2)(e)(6)(7)** (with reg. 2(3))
- C2** Sch. 3 para. 2(4)(c)-(f) applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C3** [Sch. 3 para. 2\(4\)\(c\)-\(f\)](#) amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**
- C4** Sch. 3 para. 2(5) applied (with modifications) (25.5.2007 for specified purposes, 5.7.2007 in so far as not already in force) by [Human Tissue \(Quality and Safety for Human Application\) Regulations 2007 \(S.I. 2007/1523\)](#), reg. 1(2)(3), **8(2)(e)(6)(7)** (with reg. 2(3))
- C5** Sch. 3 para. 2(5) applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C6** [Sch. 3 para. 2\(5\)](#) amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**

Commencement Information

- I6** Sch. 3 para. 2 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I7** Sch. 3 para. 2 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), **art. 2(3)(4)**, **Sch.** (with **arts. 4-6**)
- I8** Sch. 3 para. 2 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), **art. 3(3)**, **Sch.** (with **arts. 4-6**)
- I9** Sch. 3 para. 2 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), **art. 2**, **Sch.** (with **art. 4**)
- I10** Sch. 3 para. 2 in force at 1.9.2006 in so far as not already in force by [S.I. 2006/1997](#), **art. 3(2)** (with **arts. 4, 7, 8**)

- 3 (1) This paragraph applies to a licence authorising the storage of anatomical specimens.
- (2) It shall be a condition of a licence to which this paragraph applies that storage at the premises specified in the licence of the body of a deceased person for use for the purpose of anatomical examination shall not begin before that body's storage there for use for that purpose has been authorised in writing by—
- (a) the designated individual, or
 - (b) an individual who has the Authority's permission to give such authorisation (see paragraph 12).

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- (3) It shall be a condition of a licence to which this paragraph applies that any anatomical specimen which is stored at the premises specified in the licence shall be released from storage at the premises only into the possession of a person who is authorised in writing by the designated individual to have the specimen in his possession.
- (4) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give authority for the purposes of the condition in sub-paragraph (3) only if he is satisfied—
 - (a) that the person to whom authority is given is a suitable person to have the specimen in his possession, and
 - (b) that that person intends to use the specimen only for the purpose of education, training or research.
- (5) It shall be a condition of a licence to which this paragraph applies that any authority given for the purposes of the condition in sub-paragraph (3) shall specify—
 - (a) the person to whom the authority is given,
 - (b) the specimen to which the authority relates,
 - (c) the purpose for which the specimen may be used, and
 - (d) the duration of the authority.
- (6) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give such notice of any authorisation for the purposes of the condition in sub-paragraph (3) as may be specified in directions.
- (7) It shall be a condition of a licence to which this paragraph applies that such information about authorisations for the purposes of the condition in sub-paragraph (3) as may be specified in directions shall be recorded in such form as may be so specified.

Commencement Information

- I11** Sch. 3 para. 3 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, art. 2(2)(j)
- I12** Sch. 3 para. 3 in force at 1.3.2006 for specified purposes by S.I. 2006/404, art. 2(3)(4), Sch. (with arts. 4-6)
- I13** Sch. 3 para. 3 in force at 7.4.2006 for specified purposes by S.I. 2006/404, art. 3(3), Sch. (with arts. 4-6)
- I14** Sch. 3 para. 3 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, art. 2, Sch. (with art. 4)
- I15** Sch. 3 para. 3 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, art. 3(2) (with arts. 4, 7, 8)

- 4 (1) This paragraph applies to a licence authorising the activity mentioned in section 16(2)(e).
- (2) It shall be a condition of a licence to which this paragraph applies that any former anatomical specimen which is stored at the premises specified in the licence shall be released from storage at the premises only into the possession of a person who is authorised in writing by the designated individual to have the specimen in his possession.
- (3) The condition in sub-paragraph (2) does not apply to the release from storage of a specimen for the purpose of its decent disposal.

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- (4) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give authority for the purposes of the condition in sub-paragraph (2) only if he is satisfied—
- (a) that the person to whom authority is given is a suitable person to have the specimen in his possession, and
 - (b) that that person intends to use the specimen only for the purpose of education, training or research.
- (5) It shall be a condition of a licence to which this paragraph applies that any authority given for the purposes of the condition in sub-paragraph (2) shall specify—
- (a) the person to whom the authority is given,
 - (b) the specimen to which the authority relates,
 - (c) the purpose for which the specimen may be used, and
 - (d) the duration of the authority.
- (6) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give such notice of any authorisation for the purposes of the condition in sub-paragraph (2) as may be specified in directions.
- (7) It shall be a condition of a licence to which this paragraph applies that such information about authorisations for the purposes of the condition in sub-paragraph (2) as may be specified in directions shall be recorded in such form as may be so specified.

Commencement Information

- I16** Sch. 3 para. 4 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I17** Sch. 3 para. 4 in force at 1.3.2006 for specified purposes by S.I. 2006/404, **art. 2(3)(4)**, **Sch.** (with arts. 4-6)
- I18** Sch. 3 para. 4 in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(3)**, **Sch.** (with arts. 4-6)
- I19** Sch. 3 para. 4 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, **art. 2**, **Sch.** (with art. 4)
- I20** Sch. 3 para. 4 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, **art. 3(2)** (with arts. 4, 7, 8)

Power to impose conditions

- 5 The Authority may grant a licence subject to such further conditions as it thinks fit.

Modifications etc. (not altering text)

- C7** Sch. 3 para. 5 applied (with modifications) (25.5.2007 for specified purposes, 5.7.2007 in so far as not already in force) by [Human Tissue \(Quality and Safety for Human Application\) Regulations 2007 \(S.I. 2007/1523\)](#), **regs. 1(2)(3)**, **8(2)(e)(6)(7)** (with **reg. 2(3)**)
- C8** Sch. 3 para. 5 applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), **regs. 1(2)(3)**, **6** (as amended (14.7.2014) by S.I. 2014/1459, **reg. 4**)
- C9** Sch. 3 para. 5 amendment to earlier affecting provision S.I. 2012/1501 **reg. 6** (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), **regs. 1(1)**, **4**

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Commencement Information

- I21** Sch. 3 para. 5 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I22** Sch. 3 para. 5 in force at 1.3.2006 for specified purposes by S.I. 2006/404, **art. 2(3)(4), Sch.** (with arts. 4-6)
- I23** Sch. 3 para. 5 in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(3), Sch.** (with arts. 4-6)
- I24** Sch. 3 para. 5 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, **art. 2, Sch.** (with art. 4)
- I25** Sch. 3 para. 5 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, **art. 3(2)** (with arts. 4, 7, 8)

Pre-conditions to grant of licence

- 6 (1) The Authority may not grant a licence in pursuance of an application unless the following requirements are met.
- (2) The proposed designated individual must—
- be the applicant for the licence, or
 - consent to the application for the licence.
- (3) The Authority must be satisfied that the proposed designated individual—
- is a suitable person to supervise the activity to be authorised by the licence, and
 - will perform the duty under section 18.
- (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 the premises in respect of which the licence is 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—
- the applicant for the licence, and
 - where different, the proposed designated individual.
- (7) In this paragraph, references to the proposed designated individual are to the individual whom the application proposes the licence designate as the person under whose supervision the activity to be authorised by the licence is to be carried on.

Commencement Information

- I26** Sch. 3 para. 6 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
- I27** Sch. 3 para. 6 in force at 1.3.2006 for specified purposes by S.I. 2006/404, **art. 2(3)(4), Sch.** (with arts. 4-6)
- I28** Sch. 3 para. 6 in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(3), Sch.** (with arts. 4-6)
- I29** Sch. 3 para. 6 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, **art. 2, Sch.** (with art. 4)
- I30** Sch. 3 para. 6 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, **art. 3(2)** (with arts. 4, 7, 8)

Power to revoke licence

- 7 (1) The Authority may revoke a licence on application by—

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- (a) the holder of the licence, or
 - (b) the designated individual.
- (2) The Authority may revoke a licence otherwise than on an application under sub-paragraph (1) if—
- (a) it is satisfied that any information given for the purposes of the application for the licence was in any material respect false or misleading,
 - (b) it is satisfied that the designated individual has failed to discharge, or is unable because of incapacity to discharge, the duty under section 18,
 - (c) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity,
 - (d) it ceases to be satisfied that the person to whom the licence is granted is a suitable person to be the holder of the licence,
 - (e) it ceases to be satisfied that the designated individual is a suitable person to supervise the licensed activity,
 - (f) the designated individual dies, ^{F1} ...
 - (g) it is satisfied that there has been any other material change of circumstances since the licence was granted [^{F2}or
 - (h) it is not satisfied that any third country premises are suitable for carrying out activities in a manner which secures that tissues or cells imported from a third country by an importing licence holder meet standards of quality and safety equivalent to those laid down in the 2007 Regulations].

[^{F3}(3) For the purposes of sub-paragraph (2)(h), “importing licence holder”, “third country” and “third country premises” have the same meaning as in the 2007 Regulations.]

Textual Amendments

- F1** Word in Sch. 3 para. 7(2)(f) omitted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by virtue of [The Human Tissue \(Quality and Safety for Human Application\) \(Amendment\) Regulations 2018 \(S.I. 2018/335\)](#), reg. 1(2)(3), **9(4)(a)**
- F2** Sch. 3 para. 7(2)(h) and word inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by [The Human Tissue \(Quality and Safety for Human Application\) \(Amendment\) Regulations 2018 \(S.I. 2018/335\)](#), reg. 1(2)(3), **9(4)(b)**
- F3** Sch. 3 para. 7(3) inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by [The Human Tissue \(Quality and Safety for Human Application\) \(Amendment\) Regulations 2018 \(S.I. 2018/335\)](#), reg. 1(2)(3), **9(5)**

Modifications etc. (not altering text)

- C10** Sch. 3 paras. 7-11 applied (with modifications) (25.5.2007 for specified purposes, 5.7.2007 in so far as not already in force) by [Human Tissue \(Quality and Safety for Human Application\) Regulations 2007 \(S.I. 2007/1523\)](#), reg. 1(2)(3), **8(2)(e)(6)(7)** (with reg. 2(3))
- C11** Sch. 3 paras. 7-11 applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C12** Sch. 3 paras. 7-11 amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**

Commencement Information

- I31** Sch. 3 para. 7 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), art. 2(2)(j)

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- I32** Sch. 3 para. 7 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), [art. 2\(3\)\(4\)](#), **Sch.** (with arts. 4-6)
- I33** Sch. 3 para. 7 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), [art. 3\(3\)](#), **Sch.** (with arts. 4-6)
- I34** Sch. 3 para. 7 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), [art. 2](#), **Sch.** (with art. 4)
- I35** Sch. 3 para. 7 in force at 1.9.2006 in so far as not already in force by [S.I. 2006/1997](#), [art. 3\(2\)](#) (with arts. 4, 7, 8)

Power to vary licence

- 8 (1) The Authority may on application by the holder of a licence vary the licence so as to substitute another individual for the designated individual if—
- (a) the application is made with the consent of the other individual, and
 - (b) the authority is satisfied that the other individual is a suitable person to supervise the licensed activity.
- (2) The Authority may vary a licence on application by—
- (a) the holder of the licence, or
 - (b) the designated individual.
- (3) The Authority may vary a licence without an application under sub-paragraph (2) if it has power to revoke the licence under paragraph 7(2).
- (4) The powers under sub-paragraphs (2) and (3) do not extend to making the kind of variation mentioned in sub-paragraph (1).
- (5) The Authority may vary a licence without an application under sub-paragraph (2) by—
- (a) removing or varying a condition of the licence, or
 - (b) adding a condition to the licence.
- (6) The powers conferred by this paragraph do not extend to the conditions required by paragraphs 2(4), 3 and 4.

Modifications etc. (not altering text)

- C10** Sch. 3 paras. 7-11 applied (with modifications) (25.5.2007 for specified purposes, 5.7.2007 in so far as not already in force) by [Human Tissue \(Quality and Safety for Human Application\) Regulations 2007](#) ([S.I. 2007/1523](#)), [reg. 1\(2\)\(3\)](#), [8\(2\)\(e\)\(6\)\(7\)](#) (with [reg. 2\(3\)](#))
- C11** Sch. 3 paras. 7-11 applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012](#) ([S.I. 2012/1501](#)), [reg. 1\(2\)\(3\)](#), [6](#)
- C12** Sch. 3 paras. 7-11 amendment to earlier affecting provision [S.I. 2012/1501](#) [reg. 6](#) (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014](#) ([S.I. 2014/1459](#)), [regs. 1\(1\)](#), [4](#)

Commencement Information

- I36** Sch. 3 para. 8 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), [art. 2\(2\)\(j\)](#)
- I37** Sch. 3 para. 8 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), [art. 2\(3\)\(4\)](#), **Sch.** (with arts. 4-6)
- I38** Sch. 3 para. 8 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), [art. 3\(3\)](#), **Sch.** (with arts. 4-6)
- I39** Sch. 3 para. 8 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), [art. 2](#), **Sch.** (with art. 4)

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- I40** Sch. 3 para. 8 in force at 1.9.2006 in so far as not already in force by [S.I. 2006/1997](#), **art. 3(2)** (with arts. 4, 7, 8)

Power to suspend licence

- 9 (1) Where the Authority—
- (a) has reasonable grounds to suspect that there are grounds for revoking a licence, and
 - (b) is of the opinion that the licence should immediately be suspended,
- it may by notice suspend the licence for such period not exceeding three months as may be specified in the notice.
- (2) The Authority may continue suspension under sub-paragraph (1) by giving a further notice under that sub-paragraph.
- (3) Notice under sub-paragraph (1) shall be given to the designated individual or, where the designated individual has died or appears to the Authority to be unable because of incapacity to discharge the duty under section 18—
- (a) to the holder of the licence, or
 - (b) to some other person to whom the licence applies.
- (4) Subject to sub-paragraph (5), a licence shall be of no effect while a notice under sub-paragraph (1) is in force.
- (5) An application may be made under paragraph 7(1) or 8(1) or (2) notwithstanding the fact that a notice under sub-paragraph (1) is in force.

Modifications etc. (not altering text)

- C10** Sch. 3 paras. 7-11 applied (with modifications) (25.5.2007 for specified purposes, 5.7.2007 in so far as not already in force) by [Human Tissue \(Quality and Safety for Human Application\) Regulations 2007 \(S.I. 2007/1523\)](#), reg. 1(2)(3), **8(2)(e)(6)(7)** (with reg. 2(3))
- C11** Sch. 3 paras. 7-11 applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C12** Sch. 3 paras. 7-11 amendment to earlier affecting provision [S.I. 2012/1501 reg. 6 \(14.7.2014\)](#) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**

Commencement Information

- I41** Sch. 3 para. 9 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I42** Sch. 3 para. 9 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), art. 2(3)(4), **Sch.** (with arts. 4-6)
- I43** Sch. 3 para. 9 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), art. 3(3), **Sch.** (with arts. 4-6)
- I44** Sch. 3 para. 9 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), art. 2, **Sch.** (with art. 4)
- I45** Sch. 3 para. 9 in force at 1.9.2006 in so far as not already in force by [S.I. 2006/1997](#), **art. 3(2)** (with arts. 4, 7, 8)

Procedure in relation to licensing decisions

- 10 (1) Before making a decision—
- (a) to refuse an application for the grant, revocation or variation of a licence, or

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- (b) to grant an application for a licence subject to a condition under paragraph 5, the Authority shall give the applicant notice of the proposed decision and of the reasons for it.
- (2) Before making a decision under paragraph 7(2) or 8(3) or (5), the Authority shall give notice of the proposed decision and of the reasons for it to—
- (a) the holder of the licence, and
- (b) where different, the designated individual.
- (3) A person to whom notice under sub-paragraph (1) or (2) is given has the right to require the Authority to give him an opportunity to make representations of one of the following kinds about the proposed decision, namely—
- (a) oral representations by him, or a person acting on his behalf;
- (b) written representations by him.
- (4) The right under sub-paragraph (3) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 28 days beginning with the day on which the notice under sub-paragraph (1) or (2) was given.
- (5) The Authority may by regulations make such additional provision about procedure in relation to the carrying-out of functions under this Schedule as it thinks fit.

Modifications etc. (not altering text)

- C10** Sch. 3 paras. 7-11 applied (with modifications) (25.5.2007 for specified purposes, 5.7.2007 in so far as not already in force) by [Human Tissue \(Quality and Safety for Human Application\) Regulations 2007 \(S.I. 2007/1523\)](#), reg. 1(2)(3), **8(2)(e)(6)(7)** (with reg. 2(3))
- C11** Sch. 3 paras. 7-11 applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C12** Sch. 3 paras. 7-11 amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**

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- I46** Sch. 3 para. 10 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I47** Sch. 3 para. 10 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), **art. 2(3)(4)**, **Sch.** (with arts. 4-6)
- I48** Sch. 3 para. 10 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), **art. 3(3)**, **Sch.** (with arts. 4-6)
- I49** Sch. 3 para. 10 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), **art. 2**, **Sch.** (with art. 4)
- I50** Sch. 3 para. 10 in force at 1.9.2006 in so far as not already in force by [S.I. 2006/1997](#), **art. 3(2)** (with arts. 4, 7, 8)

Notification of licensing decisions

- 11 (1) In the case of a decision to grant a licence, the Authority shall give notice of the decision to—
- (a) the applicant, and
- (b) the person who is to be the designated individual.
- (2) In the case of a decision to revoke a licence, the Authority shall give notice of the decision to—

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- (a) the holder of the licence, and
 - (b) the designated individual.
- (3) In the case of a decision to vary a licence on an application under paragraph 8(1), the Authority shall give notice of the decision to—
- (a) the holder of the licence, and
 - (b) the person who is to be the designated individual.
- (4) In the case of any other decision to vary a licence, the Authority shall give notice of the decision to—
- (a) the holder of the licence, and
 - (b) the designated individual.
- (5) In the case of a decision to refuse an application for the grant, revocation or variation of a licence, the Authority shall give notice of the decision to the applicant.
- (6) Subject to sub-paragraph (7), a notice under sub-paragraph (2), (4) or (5) shall include a statement of the reasons for the decision.
- (7) In the case of a notice under sub-paragraph (2) or (4), the notice is not required to include a statement of the reasons for the decision if the decision is made on an application under paragraph 7(1) or 8(2).

Modifications etc. (not altering text)

- C10** Sch. 3 paras. 7-11 applied (with modifications) (25.5.2007 for specified purposes, 5.7.2007 in so far as not already in force) by [Human Tissue \(Quality and Safety for Human Application\) Regulations 2007 \(S.I. 2007/1523\)](#), reg. 1(2)(3), **8(2)(e)(6)(7)** (with reg. 2(3))
- C11** Sch. 3 paras. 7-11 applied (with modifications) (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), reg. 1(2)(3), **6**
- C12** Sch. 3 paras. 7-11 amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**

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- I51** Sch. 3 para. 11 in force at 20.10.2005 for specified purposes by [S.I. 2005/2792](#), **art. 2(2)(j)**
- I52** Sch. 3 para. 11 in force at 1.3.2006 for specified purposes by [S.I. 2006/404](#), art. 2(3)(4), **Sch.** (with arts. 4-6)
- I53** Sch. 3 para. 11 in force at 7.4.2006 for specified purposes by [S.I. 2006/404](#), art. 3(3), **Sch.** (with arts. 4-6)
- I54** Sch. 3 para. 11 in force at 31.7.2006 for specified purposes by [S.I. 2006/1997](#), art. 2, **Sch.** (with art. 4)
- I55** Sch. 3 para. 11 in force at 1.9.2006 in so far as not already in force by [S.I. 2006/1997](#), **art. 3(2)** (with arts. 4, 7, 8)

Permission for the purposes of the licence condition required by paragraph 3(2)

- 12 (1) This paragraph applies to a licence authorising the storage of anatomical specimens.
- (2) The reference to the Authority's permission in the condition of the licence required by paragraph 3(2) ("the authorisation condition") is to—
- (a) permission granted by the Authority on an application made, in conjunction with the application for the licence, by—
 - (i) the applicant for the licence, or

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- (ii) the person who, within the meaning of paragraph 6, is the proposed designated individual, or
- (b) permission granted by the Authority on application by—
 - (i) the holder of the licence, or
 - (ii) the designated individual.
- (3) The Authority may grant permission to an individual for the purposes of the authorisation condition only if it is satisfied that the individual is a suitable person to give authorisation under that condition.
- (4) The Authority may revoke permission granted to an individual for the purposes of the authorisation condition—
 - (a) on application by the individual, the designated individual or the holder of the licence, or
 - (b) if it ceases to be satisfied that the individual is a suitable person to give authorisation under that condition.
- (5) Before refusing an application for the grant or revocation of permission, the Authority shall give the applicant notice of the proposed refusal and of the reasons for it.
- (6) Before revoking permission under sub-paragraph (4)(b), the Authority shall give notice of the proposed revocation and of the reasons for it—
 - (a) to the individual concerned, and
 - (b) to the designated individual and, where different, the holder of the licence.
- (7) Paragraph 10(3) and (4) shall apply in relation to notice under sub-paragraph (5) or (6) as to notice under paragraph 10(1).
- (8) In the case of a decision to refuse an application for the grant or revocation of permission, the Authority shall give notice of the decision to the applicant.
- (9) In the case of a decision to grant or revoke permission, the Authority shall give notice of the decision—
 - (a) to the individual concerned, and
 - (b) to the designated individual and, where different, the holder of the licence.
- (10) Notice under sub-paragraph (8), and notice under sub-paragraph (9) of revocation under sub-paragraph (4)(b), shall include a statement of the reasons for the refusal or revocation.
- (11) Where the Authority—
 - (a) has reasonable grounds to suspect that there are grounds for revoking permission granted to an individual for the purposes of the authorisation condition, and
 - (b) is of the opinion that the permission should immediately be suspended,it may by notice suspend the permission for such period not exceeding three months as may be specified in the notice.
- (12) The Authority may continue suspension under sub-paragraph (11) by giving a further notice under that sub-paragraph.
- (13) Notice under sub-paragraph (11) shall be given to—
 - (a) the individual concerned, and

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- (b) the designated individual and, where different, the holder of the licence.

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- I56** Sch. 3 para. 12 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
I57 Sch. 3 para. 12 in force at 1.3.2006 for specified purposes by S.I. 2006/404, **art. 2(3)(4)**, **Sch.** (with arts. 4-6)
I58 Sch. 3 para. 12 in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(3)**, **Sch.** (with arts. 4-6)
I59 Sch. 3 para. 12 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, **art. 2**, **Sch.** (with art. 4)
I60 Sch. 3 para. 12 in force at 1.9.2006 in so far as not already in force by S.I. 2006/1997, **art. 3(2)** (with arts. 4, 7, 8)

Applications under this Schedule

- 13 ^{F4F5}(1) The Authority may by regulations make provision about applications under this Schedule^{F4}[^{F5}, Schedule 1 to the 2007 Regulations and Schedule 1 to the 2012 Regulations] and may, in particular, make provision about—
- the form and content of such an application,
 - the information to be supplied with such an application, and
 - procedure in relation to the determination of such an application.
- (2) An application under this Schedule shall be accompanied by such fee (if any) as the Authority may determine.]

Textual Amendments

- F4** Words in Sch. 3 para. 13(1) inserted (25.5.2007 for specified purposes, 5.7.2007 in so far as not already in force) by [Human Tissue \(Quality and Safety for Human Application\) Regulations 2007 \(S.I. 2007/1523\)](#), reg. 1(2)(3)**33**
F5 Words in Sch. 3 para. 13(1) substituted (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), regs. 1(2)(3), **25(7)**

Modifications etc. (not altering text)

- C13** Sch. 3 para. 13 applied (with modifications) (25.5.2007 for specified purposes, 5.7.2007 in so far as not already in force) by [Human Tissue \(Quality and Safety for Human Application\) Regulations 2007 \(S.I. 2007/1523\)](#), regs. 1(2)(3), **8(2)(e)(6)(7)** (with reg. 2(3))
C14 Sch. 3 para. 13 applied (with modifications) (12.7.2012 for specified purposes, otherwise 27.8.2012) by [The Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(S.I. 2012/1501\)](#), regs. 1(2)(3), **6** (as amended (14.7.2014) by S.I. 2014/1459, art. 4)
C15 Sch. 3 para. 13 amendment to earlier affecting provision S.I. 2012/1501 reg. 6 (14.7.2014) by [The Quality and Safety of Organs Intended for Transplantation \(Amendment\) Regulations 2014 \(S.I. 2014/1459\)](#), regs. 1(1), **4**

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- I61** Sch. 3 para. 13 in force at 20.10.2005 for specified purposes by S.I. 2005/2792, **art. 2(2)(j)**
I62 Sch. 3 para. 13 in force at 1.3.2006 for specified purposes by S.I. 2006/404, **art. 2(3)(4)**, **Sch.** (with arts. 4-6)
I63 Sch. 3 para. 13 in force at 7.4.2006 for specified purposes by S.I. 2006/404, **art. 3(3)**, **Sch.** (with arts. 4-6)
I64 Sch. 3 para. 13 in force at 31.7.2006 for specified purposes by S.I. 2006/1997, **art. 2**, **Sch.** (with art. 4)

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I65 Sch. 3 para. 13 in force at 1.9.2006 in so far as not already in force by [S.I. 2006/1997](#) , **art. 3(2)** (with arts. 4 , 7 , 8)

Status:

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