
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**

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.