
STATUTORY INSTRUMENTS

2007 No. 1523

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

PART 5

INSPECTION, ENTRY, SEARCH AND SEIZURE

Inspection of documents

21.—(1) A duly authorised person may require a person to produce for inspection any documents relevant to compliance with these Regulations.

(2) Where records or documents to which paragraph (1) applies are stored in any electronic form, the power under this regulation includes power to require the records or documents to be made available for inspection in a visible and legible form or in a form from which they can readily be produced in a visible and legible form.

(3) A duly authorised person may inspect and take copies of any documents produced for inspection in pursuance of a requirement under paragraph (1).

Entry and inspection of premises

22.—(1) The Authority may arrange for any premises in respect of which a licence is in force, or any relevant third party premises, to be inspected on its behalf, and for a report on the inspection to be made to it, for any of the purposes referred to in paragraph (6).

(2) The Authority shall arrange for an inspection under paragraph (1) of any premises in respect of which a licence is in force not less than once in every interval of two years.

(3) The Authority may arrange for any premises to be inspected on its behalf, and for a report on the inspection to be made to it, for the purpose of satisfying itself under regulation 11(5) that—

- (a) the premises are suitable for use for the carrying-on of a licensed activity, or
- (b) the premises are suitable to be relevant third party premises in relation to a licence.

(4) If associated with any licensed activity there occurs any serious adverse event or serious adverse reaction, the Authority shall, where it is appropriate to do so, arrange for any premises to which the licence relates and any relevant third party premises to be inspected on its behalf and for a report on the inspection to be made.

(5) For the purpose of carrying out an inspection under paragraph (1), (3) or (4), a duly authorised person may at any reasonable time enter and inspect—

- (a) any premises specified, or proposed to be specified, in the licence as premises where the licensed activities are authorised to be carried on; or
- (b) any relevant third party premises or any premises proposed to be such premises.

(6) The purposes for which an inspection may be carried out under paragraph (1) are for—

- (a) ensuring compliance by the licence holder with—

- (i) these Regulations,
- (ii) the conditions of the licence, or
- (iii) directions given under section 23(1) or 24(1) of, or paragraph 2(4) of Schedule 3 to, the 2004 Act, as applied by regulation 8;
- (b) ensuring compliance by the designated individual with the duty under regulation 12; or
- (c) ensuring compliance by a third party with a third party agreement.

Entry and search in connection with suspected offence

23.—(1) If a justice of the peace is satisfied on sworn information or, in Northern Ireland, on a complaint on oath or, in Scotland, by evidence on oath that there are reasonable grounds for believing—

- (a) that an offence under these Regulations is being, or has been, committed on any premises, and
- (b) that any of the conditions in paragraph (2) is met in relation to the premises,

he may by signed warrant authorise a duly authorised person to enter the premises, if need be by force, and search them.

(2) The conditions referred to are—

- (a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this regulation has been given to the occupier;
- (b) that the premises are unoccupied;
- (c) that the occupier is temporarily absent;
- (d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.

(3) A warrant under this regulation shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

(4) The powers exercisable by a justice of the peace under paragraph (1) are also exercisable in Scotland by a sheriff.

Execution of warrants

24.—(1) Entry and search under a warrant under regulation 23 is unlawful if any of paragraphs (2) to (4) and (6) is not complied with.

(2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.

(3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall—

- (a) produce the warrant to the occupier, and
- (b) give him—
 - (i) a copy of the warrant, and
 - (ii) an appropriate statement.

(4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall—

- (a) produce the warrant to that other person,

- (b) give him—
 - (i) a copy of the warrant,
 - (ii) an appropriate statement, and
- (c) leave a copy of the warrant in a prominent place on the premises.

(5) In paragraphs (3)(b)(ii) and (4)(b)(ii) the references to an appropriate statement are to a statement in writing containing the information set out in Schedule 3.

(6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.

(7) Where the premises in relation to which a warrant under regulation 23 is executed are unoccupied, or the occupier is temporarily absent and no other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant, shall, when leaving the premises, leave them as effectively secured as he found them.

Seizure in the course of inspection or search

25.—(1) A duly authorised person entering and inspecting premises under this Part may seize anything on the premises which he has reasonable grounds to believe may be required for purposes of the Authority's functions relating to the grant, revocation, variation and suspension of licences under Schedule 1 and to the investigation of serious adverse events and serious adverse reactions.

(2) A duly authorised person entering and searching premises under a warrant under regulation 23 may seize anything on the premises which he has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under these Regulations.

(3) Where a person has power under paragraph (1) or (2) to seize anything, he may take such steps as appear to be necessary for preserving the thing or preventing interference with it.

(4) The power under paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.

(5) Where by virtue of paragraph (1) or (2) a person seizes anything, he shall leave on the premises from which the thing was seized a statement giving particulars of what he has seized and stating that he has seized it.

Powers: supplementary

26.—(1) Any power under this Part to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.

(2) Any power under regulation 22 or 23 to inspect or search any premises includes, in particular—

- (a) power to inspect any equipment found on the premises,
- (b) power to inspect and take copies of any records found on the premises,
- (c) in the case of premises in respect of which a licence under Schedule 1 is in force, power to observe the carrying-on on the premises of the licensed activity, and
- (d) in the case of relevant third party premises in respect of which a third party agreement is in force, power to observe the carrying-on on the premises of the activity carried on pursuant to such agreement.

(3) Any power under this Part to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person's control as are necessary to enable the power of entry, inspection or search to be exercised.

Requirements when exercising power of inspection or search

27.—(1) A person’s right to exercise a power under this Part is subject to his producing evidence of his entitlement to exercise it, if required.

(2) As soon as reasonably practicable after having exercised a power under this Part to inspect or search premises, the duly authorised person shall—

- (a) prepare a written report of the inspection or search, and
- (b) if requested to do so by the appropriate person, give him a copy of the report.

(3) In paragraph (2), the “appropriate person” means—

- (a) in relation to premises in respect of which a licence is in force, the designated individual;
- (b) in relation to any relevant third party premises, the occupier.

Enforcement

28.—(1) A person commits an offence if—

- (a) he fails without reasonable excuse to comply with a requirement under regulation 21 or regulation 26(3), or
- (b) he intentionally obstructs the exercise of any right under this Part.

(2) A person guilty of an offence under this regulation is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Meaning of duly authorised person

29. In this Part, “duly authorised person”, in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision.