
STATUTORY INSTRUMENTS

1999 No. 3106

The Good Laboratory Practice Regulations 1999

Powers of entry etc.

9.—(1) For the purposes of enforcing compliance with these Regulations, a person appointed in accordance with regulation 3(4) shall have a right—

- (a) at any reasonable hour to enter any premises other than premises used only as a private dwelling house which he has reason to believe it is necessary for him to visit;
- (b) to carry out at those premises during that visit such inspections, examinations, tests and analyses as he considers necessary;
- (c) to require the production of and inspect any article or substances at the premises;
- (d) to require the production of, inspect and take copies of or extracts from any book, document, data or record (in whatever form it is held) at, or (in the case of computer data or records) accessible at, the premises;
- (e) subject to paragraph (5), to take possession of any article, substance, book, document, data, record (in whatever form they are held) at, or (in the case of computer data or records) accessible at, the premises;
- (f) to question any person whom he finds at the premises and whom he has reasonable cause to believe is able to give him relevant information;
- (g) to require any person to afford him such assistance as he considers necessary with respect to any matter within that person's control or in relation to which that person has responsibilities;
- (h) to require, as he considers necessary, any person to afford him such facilities as he may reasonably require that person to afford him,

but nothing in this paragraph shall be taken to compel the production by any person of a document of which he would, on grounds of legal professional privilege, be entitled to withhold production on an order for disclosure in an action in the High Court or, as the case may be, on an order for the production of documents in an action in the Court of Session.

(2) If a justice of the peace is satisfied by any written information on oath that there are reasonable grounds for entry into any premises other than premises used only as a private dwelling house for any purpose mentioned in paragraph (1), and—

- (a) admission to the premises has been or is likely to be refused and notice of intention to apply for a warrant under this subsection has been given to the occupier; or
- (b) an application for admission, or the giving of such notice, would defeat the object of the entry or that the premises are unoccupied or that the occupier is temporarily absent and it might defeat the object of the entry to await his return,

the justice may by warrant signed by him, which shall continue in force for a period of one month, authorise any person appointed in accordance with regulation 3(4) to enter the premises, if need be by force.

(3) A person appointed in accordance with regulation 3(4) entering any premises by virtue of paragraph (1) or of a warrant under paragraph (2) may take with him when he enters those premises

such equipment as may appear to him necessary and any person who is authorised by the GLPMA to accompany him on that visit.

(4) On leaving any premises which a person appointed in accordance with regulation 3(4) is authorised to enter by a warrant under paragraph (2), that person shall, if the premises are unoccupied or the occupier is temporarily absent, leave the premises as effectively secured against trespassers as he found them.

(5) Where, pursuant to paragraph (1)(e), a person appointed in accordance with regulation 3(4) takes possession of any article, substance, book, document, data or record, he shall leave at the premises with a responsible person a statement giving particulars of the article, substance, book, document, data or record sufficient to identify it and stating that he has taken possession of it.

(6) Persons appointed in accordance with regulation 3(4) shall, when enforcing compliance with these Regulations, have regard to any relevant provision of the Revised Guidance for the Conduct of Test Facility Inspections and Study Audits set out in Part B of the Annex to Council Directive [88/320/EEC](#) on the inspection and verification of good laboratory practice (GLP), as amended by Commission Directive [1999/12/EC](#) adapting to technical progress for the second time the Annex to Council Directive [88/320/EEC](#).