STATUTORY INSTRUMENTS

1999 No. 3106

The Good Laboratory Practice Regulations 1999

Citation and commencement

1. These Regulations may be cited as the Good Laboratory Practice Regulations 1999 and shall come into force on 14th December 1999.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

"batch" means a specific quantity or lot of a test or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character;

"experimental starting date" means the date on which the first study specific data are collected;

"experimental completion date" means the last date on which data are collected from the study;

"good laboratory practice instrument" means a document which comprises, or includes—

(a) an endorsement by a monitoring authority of a claim by a test facility that the tests that it carries out comply with the principles of good laboratory practice;

(b) a statement by a monitoring authority on the level of adherence of a test facility or a test site to the principles of good laboratory practice (including a statement that the facility or site has been found to be operating in compliance with the said principles or with these Regulations);

(c) a statement by any other person for submission, or which may be submitted, to a regulatory authority on the level of adherence of a test facility or test site, or any part of a test facility or test site, to the principles of good laboratory practice (including a statement that the facility or site operates in compliance with the said principles or with these Regulations);

(d) a statement by any person for submission, or which may be submitted, to a regulatory authority that he is a member of the United Kingdom good laboratory practice compliance programme;

(e) a report issued by a monitoring authority as a result of a study audit or a test facility or test site inspection;

(f) a statement by any person for submission, or which may be submitted, to a regulatory authority about the level of adherence of a regulatory study, or any phase of a regulatory study, to the principles of good laboratory practice (including a statement that the study, or phase of a study, was conducted in compliance the said principles or with these Regulations),

and for the purposes of this definition, the "principles of good laboratory practice" means the said principles howsoever described;

"master schedule" means a compilation of information to assist in the assessment of workload and for the tracking of studies at a test facility;

"monitoring authority" means an authority in any country or territory which is responsible (either solely or jointly with other such authorities) for monitoring the good laboratory practice compliance of test facilities;

"OECD" means the Organisation for Economic Co-operation and Development;

"OECD test guideline" means a test guideline which the OECD has recommended for use in its member countries;

"operator", in relation to a test facility, means the person having control of the test facility;

"premises", in relation to a test facility, includes field sites at which phases of regulatory studies are conducted;

"principal investigator" means an individual who, for a multi-site regulatory study, acts on behalf of the study director and has defined responsibility for one or more delegated phases of the study;

[[F1]"principles of good laboratory practice" means—

(a) the principles of good laboratory practice set out in Schedule 1, which are based on the Good Laboratory Practice Principles set out in Section II of Annex I to the European Parliament and Council Directive 2004/10/EC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances; read with

(b) the revised guidance for the conduct of test facility inspections and study audits set out in Schedule 2, which is based on part of the Revised Guidance for the Conduct of Test Facility Inspections and Study Audits in Annex I to the European Parliament and Council Directive 2004/9/EC on the inspection and verification of good laboratory practice;**]**

"quality assurance programme" means a defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with the principles of good laboratory practice;

"raw data" means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a regulatory study;

"reference item" means any article used to provide a basis for comparison with a test item;

"regulatory authority" means any authority in any country or territory with legal responsibility for aspects of the control of chemicals or items of natural or biological origin;

"regulatory study" means a non-clinical experiment or set of experiments—

(a) in which an item is examined under laboratory conditions or in the environment in order to obtain data on its properties or its safety (or both) with respect to human health, animal health or the environment;

(b) the results of which are, or are intended, for submission to the appropriate regulatory authorities; and

(c) **[**[F2]in respect of which**]** compliance with the principles of good laboratory practice is required in respect of that experiment or set of experiments by the appropriate regulatory authorities (whether or not compliance with the said principles in respect of that experiment or set of experiments is also a legislative requirement);

"short-term study" means a regulatory study of short duration with widely used, routine techniques;

"specimen" means any material derived from a test system for examination, analysis, or retention;

"sponsor" means a person who commissions, supports and/or submits a regulatory study;

"standard operating procedures" means the documented procedures which describe how to perform tests or activities normally not specified in detail in study plans or test guidelines;

"study completion date" means the date the study director signs the final report;

"study director" means the individual responsible for the overall conduct of the regulatory study;

"study initiation date" means the date the study director (first) signs the study plan;

"study plan" means a document which defines the objectives and experimental design for the conduct of a regulatory study, and includes any study plan amendments;

"study plan amendment" means an intended change to the study plan after the study initiation date;

"study plan deviation" means an unintended departure from the study plan after the study initiation date;

"test facility" means a facility which conducts or intends to conduct regulatory studies;

"test item" means an article that is the subject of a regulatory study;

"test site" means a location at which a phase of a regulatory study is conducted;

"test system" means any biological, chemical or physical system or a combination thereof used in a regulatory study;

"vehicle" means any agent which serves as a carrier used to mix, disperse, or solubilise the test or reference item to facilitate the administration or application to the test system.

(2) In these Regulations, unless the context otherwise requires, a reference—

(a) to a numbered regulation or Schedule is to the regulation in or Schedule to these Regulations bearing that number;

(b) in a regulation to a numbered or lettered paragraph is to the paragraph of that regulation bearing that number or letter; and

(c) in a paragraph to a numbered or lettered sub-paragraph is to the sub-paragraph in that paragraph bearing that number or letter.

Textual Amendments

F1 Words in reg. 2(1) substituted (27.4.2004) by The Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004 (S.I. 2004/994), regs. 1, **2(a)(i)**

F2 Words in reg. 2(1) inserted (27.4.2004) by virtue of The Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004 (S.I. 2004/994), regs. 1, **2(a)(ii)**

The Good Laboratory Practice Monitoring Authority

3.—(1) The body responsible for enforcing compliance with these Regulations shall be the Good Laboratory Practice Monitoring Authority, a body consisting of the Secretary of State for Health **[**[F3]and Social Care**]**, the National Assembly for Wales, the Scottish Ministers and the Department of Health and Social Services for Northern Ireland.

(2) The functions of the Good Laboratory Practice Monitoring Authority may be performed by any one of the Secretary of State for Health **[**[F4]and Social Care**]**, the National Assembly for Wales, the Scottish Ministers or the Department of Health and Social Services for Northern Ireland acting alone, or any two or more of them acting jointly.

(3) In accordance with the preceding provisions of this regulation, in these Regulations, "the Good Laboratory Practice Monitoring Authority" ("the GLPMA") means any one or more of the

Secretary of State for Health **[**F5and Social Care**]**, the National Assembly for Wales, the Scottish Ministers and the Department of Health and Social Services for Northern Ireland, and, in the case of anything falling to be done by the GLPMA, means any one or more of them acting as mentioned in paragraph (2).

(4) The GLPMA may appoint such persons as they think necessary for the proper discharge by them of their functions, and those persons shall be appointed upon such terms and conditions (including conditions as to remuneration, benefits, allowances and reimbursement for expenses) as the GLPMA think fit.

Textual Amendments

F3 Words in reg. 3(1) inserted (11.4.2018) by The Secretaries of State for Health and Social Care and for Housing, Communities and Local Government and Transfer of Functions (Commonhold Land) Order 2018 (S.I. 2018/378), art. 1(2), **Sch. para. 21(f)** (with art. 14)

F4 Words in reg. 3(2) inserted (11.4.2018) by The Secretaries of State for Health and Social Care and for Housing, Communities and Local Government and Transfer of Functions (Commonhold Land) Order 2018 (S.I. 2018/378), art. 1(2), **Sch. para. 21(f)** (with art. 14)

F5 Words in reg. 3(3) inserted (11.4.2018) by The Secretaries of State for Health and Social Care and for Housing, Communities and Local Government and Transfer of Functions (Commonhold Land) Order 2018 (S.I. 2018/378), art. 1(2), **Sch. para. 21(f)** (with art. 14)

Requirement to be a member or a prospective member of the United Kingdom good laboratory practice compliance programme

4. A regulatory study shall not be conducted at any premises of a test facility unless—

(a) the operator of the test facility is regarded by virtue of regulation 5 or 6 as a member or a prospective member of the United Kingdom good laboratory practice compliance programme (hereafter referred to as “the UK GLP compliance programme"); and

(b) the operator’s membership or prospective membership of that programme is or is partly in respect of those premises,

and if a regulatory study is conducted at any premises in contravention of this regulation, the operator of that test facility shall be guilty of an offence.

Prospective membership of the United Kingdom good laboratory practice compliance programme

5.—(1) An operator of a test facility shall, for the purposes of these Regulations, be regarded as being a prospective member of the UK GLP compliance programme in respect of particular premises only if—

(a) he has informed the GLPMA by notice in writing of the intention to conduct regulatory studies at those premises;

(b) the GLPMA has in writing—

(i) acknowledged receipt of that notification, and

(ii) informed the operator that he is a prospective member of the programme in respect of those premises,

and he has not ceased to be regarded as a prospective member of the programme in respect of those premises by virtue of paragraph (2).

(2) An operator of a test facility shall cease to be regarded as a prospective member of the UK GLP compliance programme in respect of particular test facility premises if—

(a) he is admitted to membership of the programme in respect of those premises by the GLPMA;

(b) he informs the GLPMA in writing that he no longer conducts or intends to conduct regulatory studies at those premises; or

(c) subject to paragraph (3), the GLPMA inform him in writing that they are not prepared to admit him to membership of the programme in respect of those premises.

(3) The GLPMA shall, before informing a prospective member of the UK GLP compliance programme they are not prepared to admit him to membership of the programme in respect of particular test facility premises—

(a) inform the prospective member that they are considering taking such action and explain to him in writing the reasons why such action is being considered;

(b) give the operator a specified period within which to make representations to the GLPMA; and

(c) consider any representations which are duly made and not withdrawn,

unless, for either of the reasons set out in paragraph (4), it is necessary for the GLPMA to inform the prospective member immediately that they are not prepared to admit him to membership of the programme in respect of those premises.

(4) The reasons referred to in paragraph (3) are [F6]...—

(a) there is a failure to adhere to the principles of good laboratory practice at those premises which, in the opinion of the GLPMA, may contribute towards precipitating a danger to animal or human health or to the environment; [F7]...

[F7](b) . . . . . .

Textual Amendments

F6 Word in reg. 5(4) omitted (27.4.2004) by virtue of The Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004 (S.I. 2004/994), regs. 1, **2(b)**

F7 Reg. 5(4)(b) and word omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), regs. 1, **2(a)**

Membership of the United Kingdom good laboratory practice compliance programme

6.—(1) Subject to paragraph (2) and except where paragraph (5), (6) or (7) applies, the operator of a test facility shall be regarded as being a member of the UK GLP compliance programme in respect of particular test facility premises if—

(a) he was regarded as being a member of the programme in respect of those premises immediately before these Regulations come into force by virtue of regulation 6 of the Good Laboratory Practice Regulations 1997 [M1]; or

(b) after having inspected those premises, the GLPMA have informed the operator in writing that they are admitting the operator to membership of the programme in respect of those premises.

(2) The operator of a test facility shall cease to be a member of the UK GLP compliance programme in respect of particular test facility premises if—

(a) he has informed the GLPMA in writing that regulatory studies are no longer conducted at those premises; or

(b) membership of the programme in respect of those premises has been withdrawn by the GLPMA in accordance with paragraph (3).

(3) Subject to paragraph (4), the GLPMA may by a notice in writing served on the operator of a test facility withdraw the operator's membership of the UK GLP compliance programme in respect of particular test facility premises if—

(a) the operator, in the opinion of the GLPMA, no longer intends to conduct regulatory studies at those premises;

(b) the operator is, in the opinion of the GLPMA, not capable of ensuring that the principles of good laboratory practice are adhered to at those premises; or

(c) at those premises there is a failure to adhere to the principles of good laboratory practice which, in the opinion of the GLPMA, may contribute towards precipitating a danger to animal or human health or to the environment.

(4) Before serving a notice on an operator of a test facility under paragraph (3)(a) or (b), the GLPMA shall—

(a) inform the operator in writing that they are considering serving such a notice and explain to him in writing the reasons why they are considering serving such a notice;

(b) give the operator a specified period within which to make representations to him; and

(c) consider any representations which are duly made and not withdrawn.

F8 …

(5) Where an operator of a test facility has ceased to be a member of the UK GLP compliance programme in respect of particular test facility premises on the grounds set out in paragraph (2)(a), or membership of the programme in respect of particular test facility premises has been withdrawn from him on the grounds set out in paragraph (3)(a), he shall again be regarded as being a member of the programme in respect of those premises if—

(a) he has informed the GLPMA by notice in writing of the intention to conduct further regulatory studies at those premises;

(b) he has become a prospective member of the programme in respect of those premises in accordance with the procedure set out in regulation 5; and

(c) after having inspected those premises, the GLPMA has informed the operator in writing of his readmission to membership of the programme in respect of those premises.

(6) Where membership of the UK GLP compliance programme has been withdrawn from an operator of a test facility in respect of particular test facility premises on the grounds set out in paragraph (3)(b), he shall again be regarded as being a member of the programme in respect of those premises if—

(a) he has informed the GLPMA by notice in writing of the intention to conduct further regulatory studies at those premises; and

(b) the GLPMA—

(i) are of the opinion that the operator is capable of ensuring that the principles of good laboratory practice are adhered to at those premises, and

(ii) have informed the operator in writing of his readmission to membership of the programme in respect of those premises.

(7) Where membership of the UK GLP compliance programme has been withdrawn from an operator of a test facility in respect of particular test facility premises on the grounds set out in paragraph (3)(c), he shall again be regarded as being a member of the programme in respect of those premises if—

(a) he has informed the GLPMA by notice in writing of the intention to conduct further regulatory studies at those premises; and

(b) the GLPMA—

(i) are of the opinion that the possible danger to animal or human health or to the environment which led to membership being withdrawn is no longer present, and

(ii) have informed the operator in writing of his readmission to membership of the programme in respect of those premises.

Textual Amendments

F8 Words in reg. 6(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), regs. 1, **2(b)**

Marginal Citations

M1 S.I. 1997/654.

Requirement to adhere to the principles of good laboratory practice

7.—(1) No person shall conduct a regulatory study at any premises of a test facility unless with regard to that study the principles of good laboratory practice are adhered to—

(a) as respects the organisational structure surrounding the study; and

(b) as respects the conditions under which the study is planned, performed, monitored, recorded, archived and reported.

(2) If the GLPMA have reasonable grounds for believing that a person has contravened paragraph (1) and is responsible for a serious deviation from the principles of good laboratory practice which may have affected the validity of a regulatory study, they may by a notice served on the operator of the test facility at whose premises the alleged contravention took place (in these Regulations referred to as a "warning notice")—

(a) state the GLPMA's grounds for believing that the person—

(i) has contravened paragraph (1), and

(ii) is responsible for a serious deviation from the principles of good laboratory practice which may have affected the validity of a regulatory study;

(b) specify the measures which, in the opinion of the GLPMA, the operator of the test facility must take in order to ensure that the serious deviation from the principles of good laboratory practice which may have affected the validity of a regulatory study will not recur;

(c) require the operator of the test facility to take those measures, or measures which are at least equivalent to them, within such period as may be specified in the warning notice; and

(d) inform the operator of the test facility of—

(i) his right of appeal against the warning notice under reglation 8,

(ii) the period within which such an appeal may be brought, and

(iii) the effect that such an appeal will have on any criminal proceedings relating to the operator's alleged failure to comply with the warning notice.

(3) Any operator of a test facility who fails to comply with a warning notice shall, unless that notice has been withdrawn by the GLPMA or cancelled by a court, be guilty of an offence.

Appeals against warning notices

8.—(1) An operator of a test facility who is aggrieved by a decision to serve a warning notice on him may appeal—

(a) in England, Wales or Northern Ireland, to a magistrates' court, and such an appeal shall be by way of complaint for an order; or

(b) in Scotland, to a sheriff, and such an appeal shall be by summary application.

(2) The period during which such an appeal may be brought is—

(a) one month from the date on which the warning notice was served on the operator desiring to appeal; or

(b) the period specified in the warning notice,

whichever ends the earlier.

(3) On an appeal against a warning notice, a magistrates' or sheriff court may either cancel or affirm the notice and, if it affirms it, may do so either in its original form or with such modifications as the court may, in the circumstances, think fit.

(4) Pending the final disposal of an appeal, unless or until the appeal is withdrawn, any criminal proceedings relating the operator's alleged failure to comply with the warning notice shall be stayed or suspended.

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 **[**F9Annex I to the European Parliament and Council Directive 2004/9/EC**]**.

Textual Amendments

F9 Words in reg. 9(6) substituted (27.4.2004) by The Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004 (S.I. 2004/994), regs. 1, **2(c)**

Disclosure of confidential information

10.—(1) A person who in the course of enforcing compliance with these Regulations gains access to commercially sensitive or other confidential information shall be guilty of an offence if, without lawful authority, he discloses that information.

(2) A person may disclose commercially sensitive or other confidential information to which he has had access in the course of enforcing compliance with these Regulations to—

(a) the European Commission;

(b) a monitoring authority;

(c) a regulatory authority;

(d) a police force;

(e) a test facility or sponsor concerned with the inspection or study audit during the course of which the GLPMA gained access to that information.

(3) For the purposes of this regulation—

(a) the names of test facilities or test sites which are or have been subject to an inspection as part of the UK GLP compliance programme;

(b) the level of adherence of a test facility or test site to the principles of good laboratory practice of those laboratories as assessed by the GLPMA; and

(c) the dates upon which study audits or test facility or test site inspections have been conducted,

shall not be considered to be confidential.

Obstruction etc. of authorised persons

11.—(1) Subject to paragraph (2)—

(a) any person who—

(i) intentionally obstructs a person appointed in accordance with regulation 3(4), or

(ii) without reasonable cause fails to comply with any requirement made of him by a person appointed in accordance with regulation 3(4),

in circumstances where that person is acting in pursuance of any of his functions under these Regulations; or

(b) any person who, in purported compliance with any such requirement as is mentioned in sub-paragraph (a)(ii), intentionally or recklessly furnishes information which is false or misleading in a material particular,

shall be guilty of an offence.

(2) Nothing in paragraph (1)(a)(ii) shall be construed as requiring any person to answer any question or give any information if to do so might incriminate him or, in the case of a person who is **[**[F10]married or a civil partner, his spouse or civil partner**]**.

Textual Amendments

F10 Words in reg. 11(2) substituted (5.12.2005) by The Civil Partnership Act 2004 (Amendments to Subordinate Legislation) Order 2005 (S.I. 2005/2114), art. 2(1), reg. 1, **Sch. 1 para. 7**

False good laboratory practice instruments

12.—(1) A person who—

(a) makes a false good laboratory practice instrument; or

(b) makes a copy of an instrument which is, and which he knows or believes to be, a false good laboratory practice instrument,

with the intention that he or another shall use it to induce a regulatory authority to accept it as a genuine good laboratory practice instrument or a copy of a genuine good laboratory practice instrument shall be guilty of an offence.

(2) A person who has in his possession—

(a) a false good laboratory practice instrument which he knows or believes to be a false good laboratory practice instrument;

(b) a copy of an instrument which he knows or believes to be a false good laboratory practice instrument,

with the intention that he or another shall supply it to a regulatory authority with the intention of inducing the regulatory authority to accept it as a genuine good laboratory practice instrument or a copy of a genuine good laboratory practice instrument shall be guilty of an offence.

(3) A person who supplies to a regulatory authority—

(a) a false good laboratory practice instrument which he knows or believes to be a false good laboratory practice instrument;

(b) a copy of an instrument which he knows or believes to be a false good laboratory practice instrument,

with the intention of inducing the regulatory authority to accept it as a genuine good laboratory practice instrument or a copy of a genuine good laboratory practice instrument shall be guilty of an offence.

(4) A good laboratory practice instrument is "false" for the purposes of this regulation if—

(a) it is not that which it purports to be for any reason including where—

(i) it purports to have been made by a person who did not make it,

(ii) it purports to have been made in the form in which it is made by a person who did not in fact make it in that form,

(iii) it purports to have been altered in any respect on the authority of a person who did not in fact authorise the alteration in that respect; or

(b) it includes information which is false or misleading in a material particular,

and a person shall be treated for the purposes of this regulation as making a false good laboratory practice instrument if he alters a good laboratory practice instrument so as to make it false in any respect (whether or not it is false in some other respect apart from that alteration).

(5) A person may be guilty of an offence—

(a) under paragraph (1) or (2) if the regulatory authority is outside the United Kingdom;

(b) under paragraph (3) if the supply is from outside the United Kingdom to a United Kingdom regulatory authority or from within the United Kingdom to a regulatory authority outside the United Kingdom.

Offences by bodies corporate and Scottish partnerships

13. Where an offence under these Regulations is committed by a body corporate or Scottish partnership and is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of—

(a) any director, manager, secretary, partner or similar officer of the body corporate or Scottish partnership; or

(b) any person who was purporting to act in any such capacity,

he as well as the body corporate or Scottish partnership shall be deemed to be guilty of that offence and he shall be liable to be proceeded against and punished accordingly.

Defence of due diligence

14. In any proceedings for an offence under any of the preceding provisions of these Regulations, it shall be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.

Penalties

15. A person guilty of—

(a) an offence under regulation 11(1)(a) shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale;

(b) an offence under regulation 12 shall be liable—

(i) on summary conviction to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or to both,

(ii) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both;

(c) any other offence under these Regulations shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale or to imprisonment for a term not exceeding three months or both.

Fees

16.—(1) The GLPMA may charge operators of test facilities and operators of test facilities shall, if so charged, pay to the GLPMA such reasonable fees as the GLPMA may determine to cover the cost of providing inspections and services under these Regulations.

(2) The GLPMA may set those fees at levels such that they meet that part of the expenditure of the GLPMA which is reasonably attributable to the cost of inspecting and providing services under these Regulations to or on behalf of the person or class of person charged but the fees must not include any element of profit.

(3) Any such fee shall be payable within fourteen days following written notice from the GLPMA requiring payment of the fee.

(4) All unpaid sums due by way of, or on account of, any fees payable under this regulation shall be recoverable as debts due to the Crown.

(5) The GLPMA may in exceptional circumstances—

(a) waive payment of any fee or reduce any fee or part of a fee otherwise payable under this regulation;

(b) refund the whole or part of any fee paid pursuant to this regulation.

Revocation

17. The Good Laboratory Practice Regulations 1997 are hereby revoked.

Alan Milburn
One of Her Majesty's Principal Secretaries of State

Department of Health
18th November 1999

Changes to legislation:
There are currently no known outstanding effects for the The Good Laboratory Practice Regulations 1999.