

ANNEX I

PART A

REVISED GUIDES FOR COMPLIANCE MONITORING PROCEDURES FOR GLP Personnel and training

(National) GLP Monitoring Authorities should:

- ensure that an adequate number of inspectors is available.

The number of inspectors required will depend on:

- (a) the number of test facilities involved in the (national) GLP compliance programme;
- (b) the frequency with which the GLP compliance status of the test facilities is to be assessed;
- (c) the number and complexity of the studies undertaken by those test facilities;
- (d) the number of special inspections or audits requested by Regulatory Authorities,

- ensure that inspectors are adequately qualified and trained.

Inspectors should have qualifications and practical experience in the range of scientific disciplines relevant to the testing of chemicals. (National) GLP Monitoring Authorities should:

- (a) ensure that arrangements are made for the appropriate training of GLP inspectors, having regard to their individual qualifications and experience;
- (b) encourage consultations, including joint training activities where necessary, with the staff of (national) GLP Monitoring Authorities in other OECD member countries in order to promote international harmonisation in the interpretation and application of GLP principles, and in the monitoring of compliance with such principles,

- ensure that inspectorate personnel, including experts under contract, have no financial or other interests in the test facilities inspected, the studies audited or the firms sponsoring such studies,

- provide inspectors with a suitable means of identification (e.g., an identity card).

Inspectors may be:

- on the permanent staff of the (national) GLP Monitoring Authority,
- on the permanent staff of a body separate from the (national) GLP Monitoring Authority, or
- employed on contract, or in another way, by the (national) GLP Monitoring Authority to perform test facility inspections or study audits.

In the latter two cases, the (national) GLP Monitoring Authority should have ultimate responsibility for determining the GLP compliance status of test facilities and the quality/acceptability of a study audit, and for taking any action based on the results of test facility inspections or study audits which may be necessary.