ANNEX I

PART B

REVISED GUIDANCE FOR THE CONDUCT OF TEST FACILITY INSPECTIONS AND STUDY AUDITS

Performance of the study

Purpose: to verify that written study plans exist and that the plans and the conduct of the study are in accordance with GLP principles.

The inspector should check that:

— the study plan was signed by the study director,

— any amendments to the study plan were signed and dated by the study director,

— the date of the agreement to the study plan by the sponsor was recorded (where applicable),

— measurements, observations and examinations were in accordance with the study plan and relevant SOPs,

— the results of these measurements, observations and examinations were recorded directly, promptly, accurately and legibly and were signed (or initialled) and dated,

— any changes in the raw data, including data stored in computers, did not obscure previous entries, included the reason for the change and identified the person responsible for the change and the date it was made,

— computer-generated or stored data have been identified and that the procedures to protect them against unauthorised amendments or loss are adequate,

— the computerised systems used within the study are reliable, accurate and have been validated,

— any unforeseen events recorded in the raw data have been investigated and evaluated,

— the results presented in the reports of the study (interim or final) are consistent and complete and that they correctly reflect the raw data.